UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	*	
	*	
v.	*	
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	*	Criminal No. 15-cr-10076-ADB
WILLIAM FACTEAU and PATRICK FABIAN,	*	
	*	
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	*	
Defendants.	*	
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MEMORANDUM AND ORDER DENYING MOTION FOR JUDGMENT OF ACQUITTAL, OR ALTERNATIVELY, A NEW TRIAL

BURROUGHS, D.J.

On July 20, 2016, a jury found William Facteau ("Facteau") and Patrick Fabian ("Fabian") (collectively, "Defendants") guilty of misdemeanor adulteration and misbranding of a medical device, and acquitted the Defendants of all other charges, including felony misbranding, conspiracy, and wire fraud. [ECF No. 432]. Currently before the Court is Defendants' post-trial motion for acquittal or a new trial, [ECF No. 437], which the government opposes, [ECF No. 497]. As no doubt evidenced by the time it has taken to resolve this motion, the Court finds the issues raised in these pleadings and at trial challenging. There is also a First Amendment overlay that further complicates the analysis. It seems clear that the statutory and regulatory scheme needs to be rethought. Currently there is no statute that specifically prohibits off-label marketing and yet the Government continues to prosecute the conduct by patching together the misbranding and adulteration regulations, thereby criminalizing conduct that it is not entirely clear Congress intended to criminalize. There are certainly important public policy considerations that warrant regulating the healthcare industry. At the same time, however, where a conviction can result in

exclusion from healthcare programs, likely a death knell for any company, it is also important for the regulatory and law enforcement regime to clearly spell out what is and is not prohibited conduct. That being said, given the facts of this case, including the acquittals on all of the felony charges, for the reasons set forth below, the motion for judgment of acquittal and a new trial, [ECF No. 437], is DENIED.

I. BACKGROUND

A. Relevant Procedural History

On April 8, 2015, a grand jury returned an eighteen-count Indictment against Defendants. [ECF No. 1 ("Indictment")]. All of the charges in the Indictment related to the sale of a medical device known as the Stratus Microflow Spacer ("Stratus"), which was sold by Acclarent, Inc. ("Acclarent"), the Defendants' former employer. See [id. ¶¶ 1–2, 5].

The Indictment charged Defendants with:

- One count of conspiracy to commit securities fraud and the offenses of adulteration and misbranding, in violation of 18 U.S.C. § 371 (Count 1);
- Three counts of securities fraud in violation of 15 U.S.C. §§ 78j(b), 78ff(a) and 17 C.F.R. § 240.10b-5 (Counts 2–4);
- Four counts of wire fraud and attempted wire fraud in violation of 18 U.S.C. §§ 1343, 1349 (Counts 5–8);
- Five counts of distributing an adulterated device into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1)–(2), 351(f)(1)(B) (Counts 9–13); and
- Five counts of introducing a misbranded device into interstate commerce in violation of 21 U.S.C. §§ 331(a), 333(a)(1)–(2), 352(a), 352(f), 352(o) (Counts 14–18).

See [Indictment]. Each of the adulteration and misbranding counts was charged as a felony and a misdemeanor. See [id.]. Shortly before the trial began, the Government dismissed Counts 2–4 and Count 8 of the Indictment, all of which related to securities fraud.

The case was tried to a jury in a twenty-seven-day trial that began on June 6, 2016. [ECF No. 364]. The jury returned its verdict on July 20, 2016, after approximately two and a half days

of deliberations. [ECF No. 432]. The jury acquitted the Defendants on Count 1 (conspiracy) and Counts 5–7 (wire fraud). [Id.]. As to Counts 9–13, which charged both felony and misdemeanor adulteration, and Counts 14–18, which charged both felony and misdemeanor misbranding, the jury acquitted Defendants on all of the felony counts but convicted on all of the misdemeanor counts. [Id.]. With regard to the misbranding convictions, the Indictment alleged three types of misbranding: false and misleading labeling; lack of adequate directions for use; and lack of required premarket notification for intended use. [Indictment ¶ 144]. The jury found that the Government had proven lack of required premarket notification for intended use but found the other two theories of misbranding not proven. [ECF No. 432].

Defendants filed a motion for a judgment of acquittal or new trial on August 1, 2016, [ECF No. 437], and filed a memorandum in support of the motion on August 31, 2016, [ECF No. 484]. The Government filed its opposition on September 30, 2016. [ECF No. 497]. Defendants filed a reply on October 17, 2016, [ECF No. 501], and the Government filed a sur-reply on November 22, 2016, [ECF No. 506].

B. Regulatory Framework

Under the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA" or "the Act"), certain medical "devices" cannot be introduced into interstate commerce without the prior approval of the Food and Drug Administration ("FDA"). 21 U.S.C. § 331. The FDCA, as amended by the Medical Device Amendments of 1976, classifies medical devices into three categories "based on the risk that they pose to the public." Medtronic, Inc. v. Lohr, 518 U.S. 470, 476 (1996) (citing 90 Stat. 539). "Devices that present no unreasonable risk of illness or injury are designated Class I and are subject only to minimal regulation by 'general controls.'" Id. at 476–77. "Devices that are potentially more harmful are designated Class II; although they

may be marketed without advance approval, manufacturers of such devices must comply with federal performance regulations known as 'special controls.'" Id. at 477. "Finally, devices that either 'presen[t] a potential unreasonable risk of illness or injury,' or which are 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' are designated Class III." Id. (alteration in original) (internal citations omitted) (quoting 21 U.S.C. § 360(a)(1)(A–C)). "Class III devices must complete a thorough review process with the FDA before they may be marketed." Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 343 (2001). In this case, it was not disputed that the Stratus was a Class III device.

The FDCA and its implementing regulations also establish processes by which a device manufacturer must obtain FDA approval. With certain exceptions, a medical device may not be introduced into interstate commerce unless it has either an FDA-approved premarket application (a "PMA") or, alternatively, a "510(k) clearance." 21 CFR §§ 814, 807.92. A PMA approval means that a device has been approved by the FDA based upon a lengthy application and evaluation process, through which the manufacturer must demonstrate that the device is safe and effective when used in accordance with its labeling. 21 CFR § 814.44. In contrast, a 510(k) clearance means that the FDA has approved the device based on a demonstration that the device is "substantially equivalent" to another device that has gone through the PMA process (a "predicate device"). 21 C.F.R. § 807.92; see Buckman, 531 U.S. at 344–45 (discussing the two regulatory routes). Accordingly, a 510(k) clearance usually allows—and is intended to allow—a manufacturer to bring a device to market more quickly than a device that goes through the PMA approval process. In order to obtain a 510(k) clearance, a medical device manufacturer must demonstrate, *inter alia*, that the device has the same intended use as the predicate device, that the

device has the same technological characteristics or is as safe and as effective as the predicate device, and that it does not raise different questions of safety or efficacy. See 21 U.S.C. § 360e(b)(1)(B); 21 C.F.R. § 807.81.

C. Adulteration and Misbranding Charges

The FDCA, 21 U.S.C. § 301 *et seq*., "was designed primarily to protect consumers from dangerous products." United States v. Sullivan, 332 U.S. 689, 696 (1948); see United States v. Dotterweich, 320 U.S. 277, 280 (1943); United States v. Dianovin Pharm., Inc., 475 F.2d 100, 103 (1st Cir. 1973). Accordingly, the FDCA regulates the marketing and sale of drugs and medical devices into interstate commerce and also sets forth criminal penalties for violations of the Act.

Section 301 of the Act prohibits the "adulteration" or "misbranding" of any food, drug, device, tobacco product, or cosmetic into interstate commerce, as well as the introduction or receipt of any such adulterated or misbranded article into interstate commerce. 21 U.S.C. § 331(a–c). The crime of adulteration or misbranding is, in its misdemeanor form, a strict liability offense, see 21 U.S.C. § 333(a)(1); Dotterweich, 320 U.S. at 281, but the offense is a felony if committed "with the intent to defraud or mislead," United States v. Orrego-Martinez, 575 F.3d 1, 4 (1st Cir. 2009) (quoting 21 U.S.C. § 333(a)(2)). To convict a defendant under the felony provisions of the Act, the Government must prove not only the defendant's knowledge of the adulteration or misbranding, but also that the defendant had a "specific intent to mislead or defraud" that was "connected to the misbranding." United States v. Mitcheltree, 940 F.2d 1329, 1351 (10th Cir. 1991). In this case, the jury found that the Defendants had the requisite knowledge but not the intent to mislead as defined, leaving the felonies unproven.

The Act defines "adulterated drugs and devices" and "misbranded drugs and devices" in Sections 501 and 502, respectively. See 21 U.S.C. §§ 351–352.

1. Adulteration

A drug or device can be "deemed adulterated" in a number of circumstances. For example, Section 501(a) provides that a drug or device is adulterated if it is "poisonous" or "insanitary," or has been prepared, packed, manufactured, or held in facilities with insanitary conditions, or whose manufacturing processes do not conform to "current good manufacturing practice" so as to ensure the product's safety. 21 U.S.C. § 351(a). Sections (b) and (c) provide that drugs whose strength, quantity or purity are misrepresented, or that fall below the recognized standards for such drugs, are also deemed "adulterated." See 21 U.S.C. § 351(b), (c). Finally, and most relevant here, "a device is 'adulterated' under the FDCA if it is required to receive premarket approval . . . from the FDA but moves in commerce even though it did not receive this PMA." United States v. Universal Mgmt. Servs., Corp., 191 F.3d 750, 754 (6th Cir. 1999) (citing 21 U.S.C. § 351(f)(1)(B)).

In this case, the adulteration offenses charged in the Indictment were based solely on Section 501(f)(1)(B) of the Act. Specifically, the Indictment alleged that Defendants, with the intent to defraud and mislead,

> caus[ed] the introduction and delivery for introduction into interstate commerce of the Stratus, which was . . . an adulterated device within the meaning of 21 U.S.C. § 351(f)(1)(B) in that it was a Class III device that lacked an FDA-approved pre-market approval . . . .

[Indictment ¶¶ 116(A), 142]. Again, the jury convicted Defendants of misdemeanor adulteration but found the Defendants not guilty of having engaged in adulteration with the requisite intent to defraud or mislead. [ECF No. 432].

2. Misbranding

Similarly, Section 502 of the Act provides that a drug or device can be deemed "misbranded" in a number of ways. See 21 U.S.C. § 352. In this case, the grand jury indicted Defendants under three separate theories of Section 502 misbranding. The Indictment alleged that Defendants, with the intent to defraud and mislead, introduced a misbranded product into interstate commerce, and that the Stratus was misbranded (1) "in that its labeling was false and misleading in violation of 21 U.S.C. § 352(a)," (2) because it "lacked adequate directions for use" in violation of 21 U.S.C. § 352(f)(1), and (3) "in that no pre-market notification was provided for the device as required by Section 510(k) . . . in violation of 21 U.S.C. § 352(o)." [Indictment ¶¶ 116(A), 144]. The jury convicted Defendants based solely on (3), which criminalizes the failure to submit a premarket notification for an intended use as required by the applicable statute. See [ECF No. 432].

Section 502(o) provides that a device is misbranded if, *inter alia*, "a notice or other information respecting it was not provided as required by . . . section 360(k) of this title . . . ." 21 U.S.C. § 352(o). The "notice" refers to the requirement, set forth in 21 U.S.C. § 360(k), that any person proposing to introduce a device into interstate commerce must, at least ninety days prior to introducing the device, submit a report to the FDA setting forth the device classification, and explaining what actions the person has taken to obtain premarket approval from the FDA. See 21 U.S.C. § 360(k). Thus, the misbranding offense charged under Section 502(o) is another way of alleging that the Defendants introduced the Stratus into interstate commerce without the appropriate premarket approvals in place.

A device's "intended use" is central to this particular variety of misbranding and the regulations set forth express guidance on how to determine a device's "intended use." Specifically, 21 C.F.R. § 801.4 provides:

> The words intended uses or words of similar import in §§ 801.5, 801.119, and 801.122 refer to the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the article is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. The intended uses of an article may change after it has been introduced into interstate commerce by its manufacturer. If, for example, a packer, distributor, or seller intends an article for different uses than those intended by the person from whom he received the devices, such packer, distributor, or seller is required to supply adequate labeling in accordance with the new intended uses. But if a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he offers it, he is required to provide adequate labeling for such a device which accords with such other uses to which the article is to be put.

21 C.F.R. § 801.4.[1]

[1] In January 2017, FDA published a final rule amending the regulation by deleting the final sentence, which the FDA hoped would clarify how it evaluates the knowledge element of intended use violations. Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses', 82 Fed. Reg. 2193, 2196 (Jan. 9, 2017). Due to industry pushback, however, the FDA has delayed the effective date of the amendment indefinitely. Clarification of When Products Made or Derived from Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses'; Partial Delay of Effective Date, 83 Fed. Reg. 11639, 11640 (Mar. 16, 2018).

II. Evidence at Trial

In reaching its verdict, the jury could have found the following facts, based on the evidence presented at trial.[2] This summary is intended to provide an overview and is supplemented as needed throughout the memorandum and order.[3]

Acclarent was founded in 2004 with the goal of having a medical device on the market within eighteen months that would aid in the treatment of sinusitis and other sinus conditions.[4] Defendant Facteau was employed at Acclarent as its CEO from November 2004 through December 2011.[5] Defendant Fabian was employed at Acclarent as its VP of Sales from August 2007 until November 2011.[6] Initially, Acclarent focused on the use of balloons as a minimally invasive approach to treating sinusitis.[7] Over time, however, the company shifted its focus to inventing a device that would treat the condition by eluting liquid to the sinuses in order to prevent obstruction and reduce inflammation.[8]

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[2] The Court presents the evidence in the light most favorable to the verdict. See United States v. Meléndez-González, 892 F.3d 9, 17 (1st Cir. 2018).

[3] As most relevant to this summary, the testifying witnesses at trial included Bradford Ader, Dr. Douglas Armstrong, Fred Barrigar, Norman Bilsbury, Dr. Peter Catalano, Dr. Cathy Chong, Dr. Martin Citardi, Kevin Convery, Dr. Douglas Hoisington, Dr. Peter Hwang, Dr. Anjun Khan, Erik Krinsky, Dr. Howard Levine, Barbara Logan, Wendy Oakes, Henry Plain, Benjamin Steffen, and Mary ("Mollie") Vanderkarr.

[4] [6/9/16 Tr. at 142:3–20].

[5] [Id. at 133:22–23; 7/7/16 Tr. at 220:17–18].

[6] [6/14/16 Tr. at 83:10–12; 7/7/16 Tr. at 220:19–20].

[7] [6/9/16 Tr. at 142:3–20; 6/13/16 Tr. at 55:17–56:3, 80:2–4; 6/22/16 Tr. at 23:16–19].

[8] [6/8/16 Tr. at 39:25–40:6; 6/13/16 Tr. at 153:21–24].

A. Design History

In 2005, the company's Scientific Advisory Board ("SAB") was actively engaged in designing a spacer that would accomplish this treatment goal by delivering drugs directly to the sinuses.[9] One witness described the ability to deliver steroids directly to the sinuses as "the holy grail for rhinology," and it was clear that developing a device to accomplish this would be lucrative.[10] The SAB discussed features of the device, including the pore size needed to elute a steroid called Kenalog-40 into the sinuses.[11] Defendant Facteau led the meetings with Acclarent's SAB and Defendant Fabian was often present.[12] It became clear that physician members of the SAB did not think there would be value in using the device with liquids, like saline, other than Kenalog-40.[13] As a result of these meetings and observations, in January 2006, members of Acclarent's executive team, including Defendant Facteau, signed off on a product specification sheet for the device indicating that a "key requirement" was that it would deliver Kenalog-40 into the sinuses for up to fourteen days.[14] In 2007, Dr. Howard Levine, an SAB

[9] [6/14/16 Tr. at 163:13–164:14; 7/12/16 Tr. at 106:2–11].

[10] [6/30/16 Tr. at 185:6–9, 187:2–9]; see also [6/15/16 Tr. at 95:10–15].

[11] [6/14/16 Tr. at 163:13–164:14].

[12] [Id. at 161:21–22, 179:7–13; 7/8/16 Tr. at 118:16–18].

[13] [6/14/16 Tr. at 166:14–167:1].

[14] [Id. at 175:2–13, 178:3–11, 178:22–179:6].

member, was the first physician to use the device in a live patient and he used it with Kenalog-40.[15]

Members of the SAB were aware that the device's pores were too large to elute saline over time, limiting the effectiveness of the device when used with saline.[16] As the company finalized the device's design, the issues with saline remained.[17] The pores, however, were sized perfectly to allow Kenalog-40, a more viscous substance, to elute through the pores and into the sinuses over ten to fourteen days.[18] It was clear that saline would simply empty out of the device within a matter of minutes, whereas Kenalog-40 would be released at a much slower rate.[19] Thus, like other available devices, the Stratus could function as a spacer, but it could not effectively elute saline and was instead clearly designed to elute Kenalog-40, a steroid.

B. Regulatory History

The company's regulatory strategy was to obtain an initial 510(k) clearance for use of the device as a spacer with saline, and then expand the indications for the device, including for delivery of drugs like Kenalog-40.[20] In September 2006, FDA granted the device—now known as the Stratus—510(k) clearance for use as a spacer that could remain in the ethmoid sinuses for

[15] [7/11/16 Tr. at 226:10–19].

[16] [6/14/16 Tr. at 167:2–9, 168:3–12].

[17] [6/8/16 Tr. at 63:4–6, 69:3–6; 6/14/16 Tr. at 86:25–87:5; 6/16/16 Tr. at 59:16–18].

[18] [6/8/16 Tr. at 62:2–8, 63:10–20, 69:3–6; 6/14/16 Tr. at 164:15–165:9].

[19] [6/8/16 Tr. at 61:19–62:8; 6/22/16 Tr. at 144:13–19, 145:1–3, 146:1–7].

[20] [6/14/16 Tr. at 184:2–15, 186:3–8; 6/15/16 Tr. at 96:5–9; 7/8/16 Tr. at 189:23–190:3].

up to fourteen days.[21] The 510(k) clearance was premised on Acclarent's description of the Stratus as a perforated device that would allow saline to moisten the sinuses.[22] Just over six months later, in April 2007, Acclarent requested additional clearance to market the Stratus for drug delivery.[23] In May 2007, FDA denied Acclarent's request to expand the Stratus' indication to include drug delivery, finding that combining drug delivery with a device would render the Stratus a combination product that would require a more extensive approval process.[24]

Acclarent continued its work developing the Stratus for drug delivery. To this end, the company had a project steering committee which included Defendant Facteau as a committee member.[25] In September 2007, committee members (including Defendant Facteau) and other senior management (including Defendant Fabian) were invited to a meeting to discuss progress on the device.[26] The meeting included a presentation compiled by different Acclarent departments which made clear that the device the company was designing and seeking to commercialize was focused on drug delivery rather than saline.[27] The presentation noted that the device would need FDA approval for a drug delivery indication.[28] Even as late as 2010,

[21] [6/13/16 Tr. at 97:13–17; 6/14/16 Tr. at 207:2–15; 6/15/16 Tr. at 83:17–22; 6/23/16 Tr. at 182:23–183:20; 6/27/16 Tr. at 111:21–112:6, 131:4–7].

[22] [6/27/16 Tr. at 116:19–117:17].

[23] [6/14/16 Tr. at 207:2–15; 6/15/16 Tr. at 83:16–22].

[24] [6/15/16 Tr. at 85:21–24; 6/27/16 Tr. at 106:4–17, 136:8–16, 142:21–143:20, 146:3–5].

[25] [6/22/16 Tr. at 18:2–11].

[26] [Id. at 41:5–20, 42:20–23, 43:5–12, 46:15–18].

[27] [Id. at 48:21–49:6, 49:8–15].

[28] [Id. at 53:16–54:5].

however, an FDA medical officer who had been reviewing Acclarent's Stratus-related applications since 2006—Dr. Anjun Khan—testified that she felt that a drug delivery indication would require a premarket approval application, rather than a simple 510(k) notification.[29] The FDA met with Defendant Facteau and other Acclarent representatives in late 2010 to discuss the Agency's decision not to approve a clinical study involving the use of the Stratus with Kenalog-40.[30] During that meeting, Acclarent told the FDA that they were seeking an indication for use of the spacer with Kenalog-40 because that off-label use was reported by "the majority of physicians" who used the device.[31] Ultimately, however, the FDA did not ever approve the Stratus for use as a drug delivery device.[32]

C. Device Launch

In 2008, Acclarent, at the direction of Defendant Facteau, decided to move forward and sell the Stratus based on its approval for the saline indication, though internal discussions demonstrate that the plan was actually to market the device for use with Kenalog-40.[33] Unlike other comparable devices, the Stratus, because of its design, could be used to deliver a drug like Kenalog-40 directly to difficult-to-reach areas of the sinuses, an attribute that physicians were interested in given the perceived benefit of being able to deliver a steroid directly into the

[29] [6/28/16 Tr. at 101:7–14, 102:15–103:10].

[30] [Id. at 104:25–105:9, 106:1–7, 107:21–23, 108:12–17].

[31] [Id. at 109:2–14].

[32] [7/5/16 Tr. at 91:24–92:2].

[33] [6/23/16 Tr. at 103:13–22; 7/6/16 Tr. at 152:12–153:15; 7/11/16 Tr. at 57:5–13, 99:11–17].

sinuses.[34, 35] Several members of the SAB, including Dr. Peter Catalano and Dr. Douglas Hoisington, disagreed with marketing the device for drug delivery and felt the company should gather additional information about its use with a steroid before launch.[36] Despite this, Acclarent, without FDA approval for a drug delivery indication, did a limited release of the Stratus in mid-2008 and then fully launched the product in September 2008.[37] A few days before launch, Defendant Facteau sent a slide presentation to several members of the SAB in which the Stratus was described as "simply a way to obtain sustained drug delivery to a targeted sinus or sinus complex."[38]

Thus, despite the limited approval obtained from the FDA, Defendants Facteau and Fabian helped Acclarent position the Stratus—both through internal training and external promotion—for drug delivery.

D. Internal Training

At a training for new sales representatives in August 2008, Defendant Facteau gave a presentation that indicated that the company was seeking to commercialize an "advanced drug delivery" treatment, referring to the Stratus.[39] Defendant Fabian was typically present at and

[34] [6/15/16 Tr. at 95:10–15].

[35] Initially the Stratus was approved for use only in the ethmoid sinuses. [6/15/16 Tr. at 162:24–163:2; 6/21/16 Tr. at 23:18–23; 6/28/16 Tr. at 30:24–31:19]. Later it was cleared for all sinuses and a larger version was eventually approved for use in the frontal sinuses. [6/15/16 Tr. at 162:24–163:2; 6/23/16 Tr. at 121:19–24; 6/27/16 Tr. at 150:11–14; 6/28/16 Tr. at 30:24–31:19].

[36] [7/8/16 Tr. at 158:16–23].

[37] [6/9/16 Tr. at 146:7–14, 170:14–20; 6/22/16 Tr. at 61:16–18, 62:4–6, 62:22–25, 79:12–20].

[38] [7/6/16 Tr. at 152:12–153:15].

[39] [6/9/16 Tr. at 146:7–24].

often participated in such new hire trainings.[40] In September 2008, Acclarent hosted a conference call for sales representatives to discuss the national launch of the Stratus.[41] Defendant Fabian attended the conference call at which Defendant Facteau presented information to the sales team.[42] Defendant Facteau's own notes from the call reflect that he planned to tell the sales team to talk to physicians about using the device with Kenalog-40 in order to provide physicians with the "opportunity for a pharmacological approach" to treating sinusitis.[43] A sales representative who attended the call, Mollie Vanderkarr, recalled being told that the company was "confident" about the efficacy of Kenalog-40.[44] Vanderkarr said that neither Defendant Facteau nor anyone else at Acclarent trained her to recommend using the Stratus with saline.[45]

During subsequent training sessions, sales representatives were told that the Stratus had only been approved in the United States for use with saline, but that the company was seeking FDA approval for use of the device with Kenalog-40.[46] Although the FDA had only approved the Stratus for use with saline, sales representatives were not taught about any benefits of using the device with saline, nor were they trained to talk to physicians about using the device with

[40] [6/9/16 Tr. at 164:4–10, 165:21–23; 6/14/16 Tr. at 83:10–25; 6/16/16 Tr. at 116:9–117:1; 6/20/16 Tr. at 22:13–21, 23:2–11].

[41] [6/9/16 Tr. at 212:20–22, 213:10–12].

[42] [Id. at 213:24–25; 6/10/16 Tr. at 39:22–40:1].

[43] [6/10/16 Tr. at 43:15–44:1, 44:25–45:12; 7/6/16 Tr. at 157:5–158:7].

[44] [6/10/16 Tr. at 39:22–40:7].

[45] [Id. at 42:18–22].

[46] [6/9/16 Tr. at 160:24–161:12; 6/20/16 Tr. at 61:2–7].

saline.[47] Sales representatives also were not trained about any benefits of using the Stratus solely as a spacer without saline or Kenalog-40, similar in function to a stent.[48] Instead, sales representatives were told that the Stratus was designed for use with Kenalog-40.[49] Sales representatives soon learned that saline—unlike Kenalog-40—would leak out of the device almost immediately because of the size of the holes, rather than slowly eluting over a period of days.[50]

Defendants Facteau and Fabian attended Acclarent's January 2009 national sales meeting.[51] At that meeting, Defendant Fabian praised sales representative Vanderkarr in connection with a role-playing exercise she performed for the national sales team.[52] Vanderkarr had been asked to participate in order to demonstrate how to get a physician interested in using the Stratus.[53] She did not recall discussing saline during the role play.[54] Sales representative Kevin Convery recalled seeing Vanderkarr's demonstration at the meeting and said she presented the Stratus as a drug delivery device.[55] Convery himself also gave a presentation at that sales meeting, attended by Defendant Facteau, in which he discussed marketing the Stratus for use as a

[47] [6/9/16 Tr. at 156:12–18; 6/14/16 Tr. at 87:15–88:7; 6/16/16 Tr. at 71:11–14; 6/20/16 Tr. at 29:3–5, 64:2–12; 6/21/16 Tr. at 24:17–25].

[48] [6/14/16 Tr. at 87:6–14; 6/20/16 Tr. at 25:24–26:6, 27:10–16, 65:5–12].

[49] [6/9/16 Tr. at 154:2–16; 6/20/16 Tr. at 25:13–23, 60:8–18].

[50] [6/9/16 Tr. at 154:12–25, 208:15–20; 6/20/16 Tr. at 28:7–14, 61:15–62:4].

[51] [7/7/16 Tr. at 76:8–12].

[52] [6/10/16 Tr. at 102:7–11, 114:2–8].

[53] [Id. at 101:21–102:3].

[54] [Id.].

[55] [6/16/16 Tr. at 82:11–19].

drug delivery device.[56] At the same meeting, Dr. Thomas Brandeisky gave a presentation, edited by members of Acclarent's marketing team and reviewed by Defendant Fabian, in which he discussed using the Stratus with steroids.[57]

Beginning in 2008, sales representatives were given a "physician discussion guide" to help them learn key discussion points to use when pitching the Stratus to physicians.[58] This guide was approved for use in the field through Acclarent's regulatory process, which included review by Defendant Fabian.[59] The guide included potential questions from physicians, as well as recommended answers, one of which was the following: "From our experience with the device outside of the U.S., the only agent that works optimally with the current [Stratus] is [Kenalog-40]."[60] The guide also stated that, "[b]ased on discussions during the development process and the 2008 Sinus Forum," physicians might want to use the device with steroids.[61]

Sales representatives, including Bradford Ader and Vanderkarr, testified that Acclarent trained them to ask physicians probing or leading questions in order to facilitate a discussion about the off-label use of the Stratus with Kenalog-40.[62] For example, when physicians asked why they should use the Stratus with saline, Vanderkarr testified that she would tell them that the

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[56] [Id. at 30:22–24, 33:15–25, 34:10–11, 34:17–35:13].

[57] [7/7/16 Tr. at 70:12–22, 72:12–73:7].

[58] [6/9/16 Tr. at 141:13–15, 195:1–2, 195:16–196:1, 196:17–23].

[59] [Id. at 196:21–23; 6/13/16 Tr. at 10:3–17, 11:10–12:3 (discussing Defendant Fabian's involvement in the approval process for marketing materials generally)].

[60] [7/12/16 Tr. at 112:19–113:16].

[61] [6/13/16 Tr. at 152:2–19].

[62] [6/9/16 Tr. at 201:14–17; 6/21/16 Tr. at 27:23–28:2].

product was approved for use with saline in the United States, but would then tell them that the device was approved for use with Kenalog-40 outside of the United States.[63] Some of these probing questions were included in the physician discussion guide.[64]

E. External Promotion

Defendants Facteau and Fabian were involved in reviewing promotional materials prior to the September 2008 full launch of the Stratus.[65] Sales representatives testified that they were not given any promotional materials for the Stratus that discussed the benefits of using the device with saline.[66] Several Acclarent sales representatives, including Ader, Convery, Barbara Logan, and Vanderkarr, testified that they never trained physicians to use the Stratus with saline and did not promote the device to physicians for use with saline.[67] Sales representatives Ader, Convery, Erik Krinsky, Logan, Benjamin Steffen, and Vanderkarr testified that they had never heard of a physician using the Stratus with saline and that all of the physicians they worked with used the device with Kenalog-40.[68]

In terms of being a spacer or a means of delivering saline, the Stratus was more expensive than other products available in the marketplace for those uses and offered no

[63] [6/9/16 Tr. at 199:4–9].

[64] [6/16/16 Tr. at 37:8–18].

[65] [7/6/16 Tr. at 143:6–144:8].

[66] See, e.g., [6/15/16 Tr. at 208:13–19; 6/20/16 Tr. at 29:15–17; 6/21/16 Tr. at 25:22–24].

[67] [6/9/16 Tr. at 179:8, 198:2–6; 6/15/16 Tr. at 208:20–209:1; 6/20/16 Tr. at 66:8–14; 6/21/16 Tr. at 28:12–17]; see also [6/9/16 Tr. at 110:13–21 (Dr. Armstrong testifying that Acclarent sales representatives never suggested that he use the Stratus with saline)].

[68] [6/10/16 Tr. at 98:16–18, 99:1–3; 6/14/16 Tr. at 105:20–106:8; 6/16/16 Tr. at 58:25–59:4; 6/20/16 Tr. at 31:12–13, 66:15–17; 6/21/16 Tr. at 28:18–29:2].

additional benefits.[69] Dr. Levine, an SAB member, testified that no one at Acclarent ever recommended that he use the Stratus with saline.[70] He testified that he exclusively used the Stratus with Kenalog-40 and had never used it with saline.[71] He also testified that he never heard of a physician using the device with saline.[72] Dr. Catalano, also an SAB member, testified that he never used the Stratus with saline and always used it with Kenalog-40 because he did not think there was any benefit to using the device with saline.[73] He stated that he would not have recommended the Stratus for use with saline to another physician, nor could he remember any physician he knew ever using it with saline.[74] He also testified that he thought the Stratus would be "useless" as a spacer or stent.[75]

Dr. Cathy Chong testified that Logan, the Acclarent sales representative assigned to her practice, described the Stratus to her as a drug delivery device.[76] Dr. Chong said that she never heard Logan discuss using the Stratus with saline, nor did Dr. Chong ever use the device with saline.[77] She also said she had never been told about the possibility of using the device solely as

[69] [6/9/16 Tr. at 114:21–115:10; 6/15/16 Tr. at 95:16–25].

[70] [7/11/16 Tr. at 230:19–25].

[71] [Id. at 139:23–140:1, 229:3–10].

[72] [Id. at 229:11–230:2].

[73] [7/12/16 Tr. at 65:18–66:3, 66:20–22].

[74] [Id. at 67:2–5, 67:11–20].

[75] [Id. at 41:5–13, 68:16–19].

[76] [6/15/16 Tr. at 124:10–17].

[77] [Id. at 125:24–126:4, 127:11–12].

a spacer, nor did she think using the device as a spacer or stent would have been effective.[78] Dr. Chong said she would not have been interested in using the device for any purpose other than steroid delivery.[79]

Dr. Peter Hwang testified that the Acclarent sales representative assigned to his territory, Sean Riley, discussed using the Stratus with steroids and it was clear to Dr. Hwang that Riley hoped he would use the device with steroids.[80] He said that Riley never recommended using the Stratus with saline or as a spacer.[81] In addition, Dr. Hwang testified that using the device simply to deliver saline would not have had any therapeutic value.[82]

Ader, Convery, and Vanderkarr testified that they had never recommended that a physician use the device simply as a spacer, without saline or Kenalog.[83] Dr. Martin Citardi testified that the Stratus would not be useful as a standalone spacer and Dr. Hoisington similarly testified that the device did not work solely as a spacer. [84, 85]

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[78] [6/15/16 Tr. at 126:5–7, 130:15–131:2]; see also [7/8/16 Tr. at 130:6–131:6 (testimony of Dr. Hoisington confirming that the device did not work with saline)].

[79] [6/15/16 Tr. at 126:8–14].

[80] [6/27/16 Tr. at 31:12–22].

[81] [Id. at 31:23–32:3].

[82] [Id. at 32:4–14].

[83] [6/14/16 Tr. at 37:19–23; 6/16/16 Tr. at 233:11–13; 6/21/16 Tr. at 28:25–29:4].

[84] [6/30/16 Tr. at 186:13–25].

[85] [7/8/16 Tr. at 130:12–131:6].

1. 2008 Sinus Forum

In July 2008, Acclarent sponsored an event called Sinus Forum to educate physicians about Acclarent products and related procedures.[86] Dr. Douglas Armstrong testified regarding his attendance at the event and his participation in a panel discussion.[87] Defendant Facteau was on the Planning Committee for the event and helped to select topics and panel members.[88] Defendant Fabian also provided input during the event's planning stages.[89] Defendant Facteau specifically directed Acclarent staff to arrange for a live demonstration of the Stratus with Kenalog-40 at the event and reviewed a proposed discussion guide that directed employees to talk to doctors there about using the Stratus with Kenalog-40.[90]

Dr. Armstrong recalled meeting Defendant Facteau at the event.[91] Defendant Fabian was also at the event.[92] Acclarent offered live video demonstrations of offsite surgical procedures in which physicians implanted the Stratus with Kenalog-40.[93] There were no demonstrations of the device being used with saline.[94] The agenda also included a panel discussion on localized drug

[86] [6/8/16 Tr. at 38:16–22, 42:23–24; 6/15/16 Tr. at 14:2–3].

[87] [6/8/16 Tr. at 39:20–24, 42:25–43:1].

[88] [6/15/16 Tr. at 5:1–21].

[89] [Id. at 20:2–12].

[90] [Id. at 6:1–9, 25:23–26:10, 30:9–31:1].

[91] [6/8/16 Tr. at 44:9–13].

[92] [6/16/16 Tr. at 18:10–11].

[93] [6/8/16 Tr. at 45:5–11, 48:15–18, 49:7–10; 6/16/16 Tr. at 21:20–22:5; 7/8/16 Tr. at 97:10–15, 98:15–18].

[94] [6/9/16 Tr. at 110:6–8; 6/15/16 Tr. at 121:5–7; 6/16/16 Tr. at 22:20–22].

delivery.[95] Dr. Armstrong said that physicians at the event were told that they were not expected to use the device with saline, and that Acclarent employees and salespeople made clear that they expected physicians to use the device with Kenalog-40.[96]

2. 2008 Annual Meeting of the American Academy of Otolaryngologists

In September 2008, Dr. Frederick Kuhn gave a presentation on behalf of Acclarent at the Annual Meeting of the American Academy of Otolaryngologists ("AAO").[97] Dr. Kuhn was a member of Acclarent's SAB.[98] Prior to the event, Dr. Catalano expressed his concerns to Defendant Facteau and other members of the SAB about launching the device at the AAO meeting given that there was limited data on the device's safety or efficacy for drug delivery.[99] Defendant Facteau disagreed with Dr. Catalano, and Dr. Kuhn's presentation went forward as planned.[100] The slides Dr. Kuhn presented at the AAO meeting described the Stratus as a spacer that provided drug delivery.[101] He specifically referenced using the Stratus with Kenalog-40.[102]

[95] [6/15/16 Tr. at 31:16–19].

[96] [6/8/16 Tr. at 50:9–16; 6/9/16 Tr. at 107:6–18, 110:9–21]; see also [7/12/16 Tr. at 131:11–19 (Dr. Levine testifying that a discussion point at the Forum was about using the Stratus for drug delivery)].

[97] [6/8/16 Tr. at 170:14–16].

[98] [6/15/16 Tr. at 23:1–5; 6/22/16 Tr. at 108:15–17; 7/7/16 Tr. at 131:8–15].

[99] [7/12/16 Tr. at 73:15–17, 74:5–11].

[100] [Id. at 75:9–20].

[101] [6/8/16 Tr. at 170:14–25; 6/30/16 Tr. at 196:7–11].

[102] [6/30/16 Tr. at 196:7–11, 201:2–6, 209:24–210:3].

3. Physician Training Sessions

Acclarent required all physicians to attend training sessions prior to purchasing the Stratus.[103] After the Sinus Forum, Dr. Armstrong attended one of these training sessions and testified that Acclarent trainers instructed physicians to use the device by filling it with Kenalog-40, not saline.[104] Convery attended nearly twenty-five of these physician training sessions.[105] Convery and other sales representatives testified that in these sessions, physicians were trained to use the Stratus with Kenalog-40 and were not trained to use the device with saline.[106] In 2009, Acclarent updated its training practices to include the use of Coffee-Mate—a non-dairy creamer that resembles Kenalog-40 in color and texture—to demonstrate the Stratus.[107] Defendant Fabian was copied on an email in which this new training practice was communicated to the sales team.[108] Dr. Levine testified that when he was trained to use the device, it was demonstrated using a white, milky substance.[109]

4. Physician Training Video

Sales representatives were given a video to show physicians in which a doctor demonstrated how to implant the Stratus and then fill it with a white substance that witnesses

[103] [6/9/16 Tr. at 31:3–9].

[104] [6/8/16 Tr. at 66:1–14].

[105] [6/16/16 Tr. at 46:12–15].

[106] [Id. at 49:14–20; 6/21/16 Tr. at 26:17–21].

[107] [6/16/16 Tr. at 50:5–11, 53:14–54:5; 6/20/16 Tr. at 63:17–24].

[108] [6/16/16 Tr. at 52:2–14].

[109] [7/11/16 Tr. at 230:7–18].

identified as Kenalog-40.[110] The video had been approved for use in the field through Acclarent's regulatory process, which included review and approval by Defendant Fabian.[111]

5. Physician Training Deck

Sales representatives were given a slide presentation to show physicians as an introduction to the Stratus.[112] The presentation itself went through the regulatory approval process, which included review and approval by Defendant Fabian.[113] This product introduction presentation did not mention saline.[114] Vanderkarr testified that she would present the slides to physicians while discussing Kenalog-40.[115] In October 2009, Defendant Fabian sent sales representatives another slide presentation to use to train physicians about the Stratus.[116] The slides contained a picture of the Stratus filled with Kenalog-40.[117] The slides did not discuss using the Stratus solely as a spacer.[118] Vanderkarr testified that she never received any training slides for use with physicians that demonstrated how to use the Stratus with saline.[119]

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[110] [6/9/16 Tr. at 175:14–18, 176:16–24; 6/15/16 Tr. at 132:5–6, 132:15–20, 133:9–11, 206:23–25, 207:18–22; 6/21/16 Tr. at 26:4–9].

[111] [6/9/16 Tr. at 177:11–14; 6/13/16 Tr. at 10:3–17, 11:10–12:3].

[112] [6/9/16 Tr. at 209:1–8].

[113] [Id. at 209:9–14; 6/13/16 Tr. at 10:3–17, 11:10–12:3].

[114] [6/9/16 Tr. at 210:20–21; 6/15/16 Tr. at 134:10–12, 208:7–19].

[115] [6/9/16 Tr. at 209:16–210:5].

[116] [6/10/16 Tr. at 63:2–15, 65:2–8].

[117] [Id. at 66:13–18; 6/15/16 Tr. at 134:13–16].

[118] [6/15/16 Tr. at 134:17–21].

[119] [6/10/16 Tr. at 69:13–16].

Sometime in 2011, Steffen recalled seeing a sales representative, Jason Elmore, give a presentation to physicians that included slides Elmore had created (without going through the marketing review process) that described the Stratus as designed to elute Kenalog-40.[120] Defendant Fabian communicated with sales representatives, including Steffen, via email, praising Elmore's sales methods.[121] Elmore was later promoted to Director of Education and Sales for Acclarent.[122]

6. Sell Sheets

In addition to the product introduction presentation, sales representatives had sell sheets that they could show physicians to share information about the Stratus.[123] The sell sheets were approved through the regulatory approval process, which included review and approval by Defendant Fabian.[124] These sell sheets had a picture that showed the Stratus being used with Kenalog-40 instead of saline.[125] The sell sheets did not mention saline.[126]

7. Field Ride-Alongs

In December 2008, Vanderkarr was on an email chain with Defendants Fabian and Facteau in which Fabian praised her for communicating with a physician about using the Stratus

[120] [6/14/16 Tr. at 111:18–23, 112:9–18, 114:14–20, 115:15–19, 116:6–7]; see also [6/21/16 Tr. at 74:16–75:1 (Bilsbury testimony regarding same slide presentation)].

[121] [6/14/16 Tr. at 111:8–25].

[122] [Id. at 124:4–5, 124:16–23].

[123] [6/9/16 Tr. at 211:3–23].

[124] [Id. at 209:12–14, 211:3–13; 6/13/16 Tr. at 10:3–17, 11:10–12:3].

[125] [6/9/16 Tr. at 211:3–17].

[126] [Id. at 211:18–19; 6/15/16 Tr. at 208:13–19].

with Kenalog-40.[127] He also participated in a ride-along with Vanderkarr in 2009 in which they visited physicians and talked to them about the Stratus.[128] Vanderkarr could not recall specific conversations she had with the physicians that she visited during Defendant Fabian's ride-along, but she testified that she would have presented the Stratus to physicians as she usually did—in other words, as a drug delivery device.[129] In a November 2009 email exchange, Defendant Fabian praised another sales representative after learning that he had recommended the device for use with Kenalog-40, saying, "This is a great example of how we all should approach every surgeon in every case, every day."[130] After accompanying sales representatives Ader and Norman Bilsbury on separate ride-alongs in 2009, Defendant Fabian sent them each an email encouraging them to pitch the Stratus as an "extension of medical management" when meeting with doctors.[131] Ader and Bilsbury testified that sales representatives were trained to understand that "medical management" referred to treating patients with medicine or drugs, not saline.[132]

III. ACQUITTAL UNDER RULE 29

A. Legal Standard

To prevail on a motion for judgment of acquittal under Federal Rule of Criminal Procedure 29, a defendant must "show that the evidence presented at trial, even when viewed in

[127] [6/10/16 Tr. at 126:25–127:3, 127:8–10, 129:5–20].

[128] [Id. at 180:25–181:23, 183:21–23].

[129] [6/9/16 Tr. at 179:8, 198:2–6, 200:18–201:6; 6/10/16 Tr. at 183:1–4, 183:21–23]

[130] [6/10/16 Tr. at 133:4–5, 136:11–14, 137:25–138:9].

[131] [6/21/16 Tr. at 35:11–15, 35:20–23, 37:2–8, 70:12–19, 71:9–15].

[132] [Id. at 37:8–18, 51:21–24, 71:23–72:3, 72:20–73:1, 149:14–16]; see also [6/22/16 Tr. at 33:20–23 (Barrigar testimony regarding same)].

the light most favorable to the government, did not suffice to prove the elements of the offenses beyond a reasonable doubt." United States v. Acevedo, 882 F.3d 251, 257 (1st Cir. 2018). On a Rule 29 motion, the Court does not "weigh the evidence or make any credibility judgments, as those are left to the jury." United States v. Merlino, 592 F.3d 22, 29 (1st Cir. 2010) (citing United States v. Ayala-Garcia, 574 F.3d 5, 11 (1st Cir. 2009)). Instead, the Court "resolve[s] all credibility disputes in the verdict's favor," id. (quoting United States v. Olbres, 61 F.3d 967, 970 (1st Cir. 1995)), and "examine[s] the evidence—direct and circumstantial—as well as all plausible inferences drawn therefrom, in the light most favorable to the verdict," United States v. Meléndez-González, 892 F.3d 9, 17 (1st Cir. 2018) (internal quotation marks omitted).

The verdict will be upheld if it is "supported by a plausible rendition of the record." Merlino, 592 F.3d at 29 (quoting United States v. Bristol-Martir, 570 F.3d 29, 38 (1st Cir. 2009)). "If the evidence viewed in the light most favorable to the verdict gives equal or nearly equal circumstantial support to a theory of guilt and a theory of innocence of the crime charged," however, the Court must reverse the conviction because "where an equal or nearly equal theory of guilt and a theory of innocence is supported by the evidence viewed in the light most favorable to the prosecution, a reasonable jury *must necessarily entertain* a reasonable doubt." United States v. Burgos, 703 F.3d 1, 10 (1st Cir. 2012) (quoting United States v. Flores-Rivera, 56 F.3d 319, 323 (1st Cir. 1995)).

B. Defendants' Asserted Grounds for Acquittal

In their motion for acquittal, Defendants set forth four separate grounds for acquittal: (1) that the Government's reliance on truthful, non-misleading speech to support Defendants' conviction violates the First Amendment; (2) that Defendants' Due Process rights were violated by being held strictly liable for non-fraudulent conduct; (3) that the Government failed to provide

sufficient evidence to prove adulteration or misbranding in connection with the shipments alleged in the sole counts of conviction; and (4) that the jury's adulteration and misbranding verdicts were mutually exclusive. [ECF No. 484 at 4–5].

1. Alleged First Amendment Violation

The Defendants assert that the convictions in this case violate the First Amendment because they rely on evidence of truthful, non-misleading speech. [ECF No. 484 at 6–7]. The gist of the argument is that because the evidence of intended use consisted of only truthful, non-misleading speech and internal communications not shared with customers, there was no criminal actus reus beyond protected speech to support the convictions. [ECF No. 484 at 7–8]. The Government responds that the speech served only as evidence of the crime, while the crime itself was the distribution of a device that lacked FDA approval or premarket notice for the intended use of drug delivery. [ECF No. 497 at 6–7].

The Supreme Court has held that "[s]peech in aid of pharmaceutical marketing . . . is a form of expression protected by the Free Speech Clause of the First Amendment." Sorrell v. IMS Health Inc., 564 U.S. 552, 557 (2011). Speech that is false or misleading, however, is not protected. Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm'n, 447 U.S. 557, 576 (1980) (Brennan, J., concurring); Va. State Bd. of Pharmacy v. Va. Citizens Consumer Council, 425 U.S. 748, 771 (1976) (citing Gertz v. Robert Welch, Inc., 418 U.S. 323, 340 (1974)). Speech alone may not constitute an actus reus in the context of a misbranding action but, as the Supreme Court has recognized, "[t]he First Amendment . . . does not prohibit the evidentiary use of speech to establish the elements of a crime or to prove motive or intent." Wisconsin v. Mitchell, 508 U.S. 476, 489 (1993).

The First Circuit has not yet considered the line between off-label promotion that is truthful and non-misleading and the FDA's ability to regulate speech relative to off label promotion. Courts within the Second Circuit have considered this issue in two seminal cases, United States v. Caronia, 703 F.3d 149 (2d Cir. 2012), and Amarin Pharma, Inc. v. United States Food & Drug Administration, 119 F. Supp. 3d 196 (S.D.N.Y. 2015).

In Caronia, the Second Circuit held that while truthful, non-misleading commercial speech alone may not sustain a criminal conviction, "[o]ff-label promotional statements could . . . presumably constitute evidence of an intended use of a drug that the FDA has not approved." Caronia, 703 F.3d at 155. The Second Circuit noted that at trial, the Government had "treated [the defendant's] promotional speech as more than merely evidence of a drug's intended use" such that the defendant was convicted of a crime in which the actus reus was protected speech. Id. at 155, 158. In rejecting the Government's argument that the defendant's speech was only used as evidence of intent concerning the misbranding charge, the Second Circuit held that the Government "never argued in summation or rebuttal that the promotion was evidence of intent" and that "the record makes clear that the [G]overnment prosecuted [the defendant] *for* his promotion and marketing efforts." Id. at 161.

Amarin, a civil case, involved a pharmaceutical company's challenge to a communication from the FDA which suggested that the company's product might be misbranded if the company used certain statements to market the product. Amarin, 119 F. Supp. 3d at 212. The FDA represented to the court that it had reserved the right to institute a misbranding action against the company "where the only conduct on which that action would be based are truthful and non-misleading statements promoting off-label use." Id. at 223. Consistent with Caronia, the court

found that truthful and non-misleading off-label speech cannot serve as the sole basis for a misbranding action. Id. at 229.

In both Caronia and Amarin, the courts articulated a distinction between truthful, non-misleading off-label speech alone, and speech in connection with the act of mislabeling for an unapproved intended use. Caronia, 703 F.3d at 161 ("Even assuming the government can offer evidence of a defendant's off-label promotion to prove a drug's intended use and, thus, mislabeling for that intended use, that is not what happened in this case."); Amarin, 119 F. Supp. 3d at 228 ("Caronia does not limit the Government's ability to use promotional speech to establish intent in a misbranding action with a proper *actus reus*."); see United States *ex rel.* Polansky v. Pfizer, Inc., 822 F.3d 613, 615 n.2 (2d Cir. 2016) ("Caronia left open the government's ability to prove misbranding on a theory that promotional speech provides evidence that a drug is intended for a use that is not included on the drug's FDA-approved label.").

Unlike the district court in Caronia, here the Court clearly instructed the jury that it could not convict Defendants simply for making truthful, non-misleading off-label statements. As examples, the instructions to the jury included the following:

- You may not convict a Defendant of a crime based solely on truthful, non-misleading statements promoting an FDA-cleared or approved device, even if the use being promoted is not a cleared or approved use. [ECF No. 436 at 26 ("Jury Instructions")].

- Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent. [Id. at 27].

- Off-label promotional statements can constitute evidence of an intended use, although truthful, non-misleading speech alone cannot be the basis for a criminal conviction. [Id.].

Cf. Caronia, 703 F.3d at 159 ("The district court, in its jury charge, reinforced the idea that [defendant's] promotional speech was enough to support a guilty verdict . . . ."). Further, rather than reinforce the idea that speech itself can be a crime, the Court's instructions to the jury on misbranding related to the failure to file premarket notification also omitted any reference to speech at all: "[A] medical device is also misbranded if the manufacturer introduces the device into interstate commerce for an intended use that is significantly different from the use covered by its 510(k) clearance and without submitting a new premarket notification to the FDA regarding the different intended use." [Jury Instructions at 36].

In addition, unlike in Caronia, the Government discussed Defendants' speech in the context of establishing their objective intent regarding the intended use of the Stratus. See Caronia, 703 F.3d at 161. For example, in its closing argument the Government asked the jury to "look at all of the circumstances surrounding the distribution of the device to figure out what would be the intended use of the device." [7/14/16 Tr. at 78:10–13]. The Government also identified failing to submit premarket notification, rather than speech, as the actus reus of the misbranding conviction: "Lack of required pre-market notification for its intended use. So Stratus is intended for use as a drug delivery device. There's no 510(k) for the Stratus for the intended use of a drug delivery device." [Id. at 114:23–115:2].

The jury's instructions and the Government's arguments at closing clearly indicated to the jury that the actus reus supporting the conviction had to be the Defendants' failure to submit a premarket notification for the intended use of drug delivery. It is an "almost invariable assumption of the law that jurors follow their instructions . . . ." Richardson v. Marsh, 481 U.S. 200, 206 (1987); United States v. Aboshady, 951 F.3d 1, 11 (1st Cir. 2020) (citing Richardson). Therefore, the Defendants' speech cannot be assumed to be the basis for the conviction. Rather,

the instructions and argument made clear that speech could only be used to deduce the Defendants' objective intent with regard to the intended use of the Stratus. See Wisconsin, 508 U.S. at 489. Here, the use of speech to actively market and promote the device for off-label use, as Defendants did, was evidence of their intent that the device be used for a purpose that the FDA had not approved and was not itself the crime. The Court therefore finds that Defendants' First Amendment rights were not violated by the conviction.[133]

2. Alleged Due Process Violation

Defendants next claim that their Due Process rights were violated by misdemeanor adulteration and misbranding convictions predicated on strict liability. [ECF No. 484 at 9]. In particular, Defendants argue that (1) the meaning of "intended use" is impermissibly vague, (2) the Government's use of the company's internal communications exacerbated this vagueness by improperly expanding the scope of evidence used to determine intended use, and (3) novel theories were used to hold Defendants strictly liable where scienter was not required. [Id. at 9–10]; see also [ECF No. 185 at 6–10; ECF No. 194]. In response, the Government states that both the Supreme Court and the First Circuit have upheld the statute at issue against challenges of vagueness, [ECF No. 497 at 25–26], that evidence of intended use is not limited to external

[133] The Court is cognizant of arguments made by Amicus Curiae Medical Information Working Group that truthful, non-misleading statements about off-label use should not be restricted due to the importance of allowing manufacturers to provide health care practitioners with important information about their products. See [ECF No. 491 at 22]. The jury verdict and the Court's ruling herein, however, do not serve to chill such speech, which FDA guidance permits. See, e.g., FDA, Revised Draft Guidance for Industry: Distributing Scientific and Medical Publications on Unapproved New Uses – Recommended Practices (Feb. 2014); FDA, Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices (Dec. 2011); FDA, Guidance for Industry: Industry-Supported Scientific and Educational Activities, 62 Fed. Reg. 64,093 (Dec. 3, 1997). Regardless of the merits of this policy argument, this is a change that would have to be effected through the FDA or Congress.

communications, [id. at 32–35], and that the lack of a scienter requirement does not violate Due Process, [id. at 37].[134]

a. Vagueness Challenge

"The Due Process Clause 'mandates that, before any person is held responsible for violation of the criminal laws of this country, the conduct for which he is held accountable [must] be prohibited with sufficient specificity to forewarn of the proscription of said conduct.'" United States v. Lachman, 387 F.3d 42, 56 (1st Cir. 2004) (quoting United States v. Anzalone, 766 F.2d 676, 678 (1st Cir. 1985)). "The mere fact that a statute or regulation requires interpretation does not render it unconstitutionally vague." Id. The First Circuit recently reversed a decision from the District of Massachusetts that overturned a misbranding conviction on vagueness grounds. See United States v. Stepanets, 879 F.3d 367, 374 (1st Cir. 2018). As the First Circuit noted in its opinion, "no one cites a case—and we know of none—holding any key []FDCA provision void for vagueness . . . ." Stepanets, 879 F.3d at 374.

Beyond the FDCA, Defendants assert that the meaning of "intended use" in FDA regulations, in particular 21 C.F.R. § 801.4, results in "confusion, ambiguity, and [a] corresponding lack of fair notice . . . ." [ECF No. 484 at 9–10]. Defendants further argue that the examples provided in the regulation make clear that manifestations of objective intent are limited to external communications ("labeling claims, advertising matter"), and that, in this case, the Government and the FDA inappropriately expanded this to include internal communications. [ECF No. 484 at 12–13]. For example, Defendants note that in addition to evidence of external communications that promoted an unapproved intended use of the device, the Government

[134] The Court has already addressed, supra Section III.B.1, the First Amendment arguments that Defendants incorporate by reference from their motions to dismiss, see [ECF No. 484 at 9], and will therefore focus on Defendants' vagueness and strict liability challenges.

presented evidence of internal design discussions about the Stratus, as well as internal communications about how to market the Stratus as a drug delivery device. See, e.g., [6/9/16 Tr. at 146:7–24 (Defendant Facteau gave a presentation to new sales representatives on using the Stratus for drug delivery); 6/9/16 Tr. at 196:17–23, 6/13/16 Tr. at 10:3–17, 11:10–12:3, 150:6–14, 6/16/16 Tr. at 37:8–18, 6/21/16 Tr. at 27:23–28:2 (Defendant Fabian approved a physician discussion guide, which trained sales representatives to ask physicians questions to elicit discussions about using the Stratus for drug delivery)].

Section 801.4 of the Code of Federal Regulations defines intended use as referring to an "objective intent." 21 C.F.R. § 801.4. The regulation goes on to state that "intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and provides examples of such expressions that "may" show objective intent. Id. Those examples include "labeling claims, advertising matter, or oral or written statements" as well as "circumstances" demonstrating that the device is "offered and used for a purpose for which it is neither labeled nor advertised." Id. The jury's instructions were consistent with the regulation:

> The term "intended use" refers to the objective intent of the manufacturer or seller of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised.

[Jury Instructions at 27].[135]

[135] As noted supra n.1, the FDA has suspended implementation of a revision to § 801.4 that would remove the final sentence of the regulation (regarding whether "a manufacturer knows, or has knowledge of facts that would give him notice that a device introduced into interstate commerce by him is to be used for conditions, purposes, or uses other than the ones for which he

In a 1957 case involving misbranding, the First Circuit upheld a conviction where one of the regulations in question defined "intended use" in the context of drugs using language nearly identical to the language in § 801.4 that defines "intended use" for devices. V.E. Irons, Inc. v. United States, 244 F.2d 34, 45 (1st Cir. 1957). Compare 21 C.F.R. § 201.128, with 21 C.F.R. § 801.4. Notably, the First Circuit applied the regulation to the case and affirmed the convictions without questioning the regulation itself. See V.E. Irons, 244 F.2d at 44, 46.

Similar to the instant case, in V.E. Irons one of the counts of conviction was a misdemeanor that did not require the Government to prove that the defendants made false or misleading statements, relying instead on the failure to include certain information on the label. See id. at 36 (stating that Count I was a misbranding charge for failure to include required information on labeling); id. at 45–46 (affirming conviction and noting that Count I did not require the Government to prove false or misleading statements). In V.E. Irons, the First Circuit held that courts may look to "all relevant sources in order to ascertain what is the 'intended use' of a drug" and that it was "entitled to utilize all of appellants' literature as well as the oral representations made by the defendant at his lectures or by authorized sales distributors" in order to determine the intended use of the drug in question. 244 F.2d at 44. Although its opinion did not explicitly delineate what materials it intended to bring within the scope of "all relevant sources," it did not articulate any limitations on the concept. See id. Nor did it say that internal communications could not be reviewed, only that the court planned to review literature (including written, printed, and graphic material used by sales distributors) and oral representations made at lectures, all of which would qualify as external communications. See id.

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offers it . . . ."), and the language therefore remains applicable. The Court nonetheless will proceed by analyzing other relevant language within the regulation.

Defendants cite a number of cases in an effort to support their claim that evidence of intended use is limited to "externally directed statements." [ECF No. 484 at 14–15]. These cases, however, do not directly support their position. For example, although a 1995 case from the Eighth Circuit said that promotional materials are relevant to intent, it did not hold that such materials were the only relevant source of evidence relative to intent. United States v. Articles of Drug for Veterinary Use, 50 F.3d 497, 500 (8th Cir. 1995). Defendants also rely on Brown & Williamson Tobacco Corp. v. FDA, 153 F.3d 155, 163 (4th Cir. 1998), but that opinion omits a significant portion of a quotation from the lower court's opinion which states in full: "Although it is true that no court has ever found that a product is 'intended for use' or 'intended to affect' within the meaning of the FDCA absent manufacturer claims as to that product's use, no court has held that intended use can be established solely by promotional representations." Coyne Beahm, Inc. v. United States FDA, 966 F. Supp. 1374, 1390 (M.D.N.C. 1997). In contrast, the Government cites sufficient support from other jurisdictions for the proposition that objective evidence of intended use is not limited to external communications. See [ECF No. 497 at 32–34].[136]

[136] Defendants cite to a 2002 letter from Daniel E. Troy, FDA Chief Counsel, to a manufacturer seeking FDA guidance regarding the intended use of a specific manufacturer's medical device. [ECF No. 484 at 17; ECF No. 501 at 19; ECF No. 485-1 at 33–39 (letter from Daniel E. Troy to Jeffrey N. Gibbs)]. FDA regulations, however, make clear that such informal communications are not binding on the Agency:

> A statement or advice given by an FDA employee orally, or given in writing but not under this section or § 10.90, is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

21 C.F.R. § 10.95(k).

The language of § 801.4 also fails to establish the limitation urged by Defendants. When engaging in statutory construction, courts "ordinarily assume, 'absent a clearly expressed legislative intention to the contrary,' that 'the legislative purpose is expressed by the ordinary meaning of the words used.'" Jam v. Int'l Fin. Corp., 139 S. Ct. 759, 769 (2019) (quoting Am. Tobacco Co. v. Patterson, 456 U.S. 63, 68 (1982)). The regulation provides examples of what may be used to determine "objective" intent, some of which are directed externally ("labeling claims, advertising matter"), and some of which ("oral or written statements" and "circumstances") are not limited to external communications. See 21 C.F.R. § 801.4.

"Objective" is defined as "[a] thing or class of things external to or independent of the mind . . . ."[137] This definition brings internal company communications within the field of materials that may be considered to determine a party's objective intent with regard to an intended use. "Subjective," in contrast, is defined as "[e]xisting in the mind only, without anything real to correspond to it . . . ."[138] A party's unexpressed thoughts would therefore fall within the realm of subjective intent, whereas internal communications are outward expressions of intent. As noted in a 1994 opinion from the District of Rhode Island:

> It is the objective intent of the vendor, not the vendor's subjective explanations and disclaimers, which determines the intended use of a product, as gleaned not only from the vendor's statements, but from any relevant source, such as promotional material, advertising, labeling and other circumstances surrounding the distribution of the article.

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[137] *Objective*, Oxford English Dictionary Online, https://www.oed.com/view/Entry/129634?redirectedFrom=objective#eid (last visited September 11, 2020).

[138] *Subjective*, Oxford English Dictionary Online, https://www.oed.com/view/Entry/192702?redirectedFrom=subjective#eid (last visited September 11, 2020).

United States v. Kasz Enters., 855 F. Supp. 534, 542 (D.R.I. 1994) (discussing analogous provision at 21 C.F.R. § 201.128). The Court finds that, per the plain language of the regulation, which is not contradicted by case law or practice, evidence of a party's objective intent is not limited to external communications, but can include any "oral or written statements" and "circumstances," whether directed internally or externally.[139]

Further, even if the Court were to find that § 801.4 limits evidence of intended use solely to external communications, the Government provided ample examples of external communications that evidenced Defendants' objective intent to sell the Stratus as a drug delivery device, despite not submitting a PMA or premarket notification for that intended use. See supra Section II.E.

In addition, if the Government had been limited to using external communications to prove the Defendants' objective intent with regard to intended use of the device, the Government nonetheless would have been permitted to present evidence of internal communications to support their alternative theory of the Defendants' intent to defraud or mislead. See [Jury Instructions at 42 ("It can be difficult to prove a defendant's state of mind directly, but a defendant's state of mind can be proved indirectly from the surrounding circumstances. This includes things such as what the defendant said or did, how the defendant acted, and any other facts or circumstances in evidence that bear on the defendant's intent.")]. The Government was

[139] Defendants suggest that "[i]f strategic development plans, design history, and related communications could be considered evidence of 'intended use,' all manufacturers seeking improvement of their product line would, absurdly, be criminals." [ECF No. 484 at 13–14]. The facts in this case do not support such an expansive view. The totality of the evidence submitted by the Government, including Acclarent's internal and external materials, was sufficient to prove that Defendants not only contemplated design improvements that would require FDA approval but designed and made those improvements, marketed them, and made a conscious decision not to submit a PMA or premarket notification for this new intended use despite their obligation to do so. See supra Section II.

not prohibited from pursuing these alternative theories or from presenting evidence in support of each. United States v. Mubayyid, 658 F.3d 35, 70 (1st Cir. 2011) ("It is well established that an indictment may charge alternative theories of guilt in the conjunctive, and that, '[w]hen a jury returns a guilty verdict on an indictment charging several acts in the conjunctive, the verdict stands if the evidence is sufficient with respect to any one of the acts charged.'" (quoting United States v. Murray, 621 F.2d 1163, 1171 n.10 (1st Cir. 1980))).

b. Strict Liability Challenge

Finally, the Court does not find the Defendants' strict liability arguments persuasive in light of its findings regarding the lack of vagueness in § 801.4's definition of intended use. Supreme Court precedent also supports the Court's findings in the context of corporate officer liability. In United States v. Park, the Supreme Court held that a corporate officer could be convicted for misdemeanor adulteration even without proof that he had knowledge of wrongdoing. 421 U.S. 658, 672–73 (1975). The Supreme Court specifically stated that "Congress has seen fit to enforce the accountability of responsible corporate agents dealing with products which may affect the health of consumers by penal sanctions cast in rigorous terms, and the obligation of the courts is to give them effect so long as they do not violate the Constitution." Id. at 673; see also United States v. Stepanets, 362 F. Supp. 3d 22, 24 (D. Mass. 2019) (declining to overrule Park on Due Process grounds). This clearly indicates that the Supreme Court did not find that holding a defendant strictly liable as a responsible corporate officer violated Due Process.

As a result, Defendants' assertion that the strict liability offenses for which they were convicted violate Due Process is unavailing. See [ECF No. 484 at 26–27]; see also United States v. Freed, 401 U.S. 601, 607 (1971) (noting that a mens rea requirement is often not required for

criminal "activities affecting public health, safety, and welfare." (citing Morissette v. United States, 342 U.S. 246, 251 (1952))); United States v. DeCoster, 828 F.3d 626, 633 (8th Cir. 2016) (affirming a conviction under the FDCA where there was no mens rea requirement and noting that a maximum statutory penalty for a misdemeanor of one year does not violate Due Process). The Court therefore finds that Defendants' convictions do not violate Due Process.[140]

3. Sufficiency of Evidence on Adulteration and Misbranding

The Defendants next claim that acquittal is warranted because the Government provided no evidence that Acclarent "created a new 'intended use' of drug delivery for the Stratuses shipped" in the ten transactions alleged in the Indictment. [ECF No. 484 at 28]; see also [Indictment ¶¶ 142, 144]. More specifically, Defendants argue that the Government had to link

[140] Very fundamentally, our criminal justice system is premised on the idea that one should be punished for unlawful acts undertaken with some level of criminal intent. The Park or responsible corporate officer doctrine, however, allows individuals to be criminally prosecuted even absent any proof of the individual's knowledge about or participation in the charged offense. See 421 U.S. at 673. This approach, which is typically used in cases involving the food and drug industries, is often justified by the need to hold executives to the highest standard when they are responsible for goods which directly affect people's lives and health, and where the consumer is in no position to ensure or evaluate the safety of the drug or food item at issue. See Freed, 401 U.S. at 607. Even so, there is something troubling about a criminal conviction based on strict liability in a situation where the accused may legitimately have had no idea what was going on far below him on the corporate ladder, but is nonetheless held criminally responsible simply by virtue of his position. This unease with the idea of strict liability in the criminal context is reflected in United States v. DeCoster, 828 F.3d 626 (8th Cir. 2016), cert denied, 137 S. Ct. 2160 (2017). In that case, Judge Murphy, writing for the majority, found both that the responsible corporate officer doctrine implies an aspect of blameworthiness, but also that the record showed that the defendants in that case were "liable for negligently failing to prevent the salmonella outbreak" at issue in the case. Id. at 633. Judge Gruender concurred but wrote "separately in order to make clear [his] view that Park requires a finding of negligence in order to convict a responsible corporate officer" and joined Judge Murphy only because he and the district court found the defendants negligent. Id. at 637 (Gruender, J., concurring). Finally, Judge Beam dissented based on his belief that Due Process requires mens rea for a criminal conviction. Id. at 640 (Beam, J., dissenting). This Court, however, does not need to grapple with the limits of Park and strict liability in the context of this case because the evidence here clearly demonstrated that Defendants directly and personally participated in the charged conduct. See supra Section II.

external communications about use of the Stratus for drug delivery to a particular customer or account. [ECF No. 484 at 29–30].[141] In opposing this claim, the Government states that "it was reasonable for the jury to conclude that *every* distribution of Stratus was a crime" based on Acclarent's nationwide promotion of the device for a new intended use and the company's failure to obtain FDA approval for that use. [ECF No. 497 at 42–43].

As noted in Section III.B.2, supra, the Court has determined that there was sufficient evidence for the jury to find beyond a reasonable doubt that the Defendants' objective intent was to promote the Stratus for drug delivery but without the required notice under § 352(o). With Defendants' objective intent establishing a new intended use for which they did not notify the FDA, the sole remaining question is whether they introduced the misbranded device into interstate commerce under 21 U.S.C. § 331(a). Nowhere in § 801.4 is there a requirement that evidence of intended use be linked to a specific customer to establish objective intent. See 21 C.F.R. § 801.4. Nor does the regulation require a party to intend that a device be used a certain way in a certain state. See id.

Defendants cite "a long line of cases" that do not, in fact, support their novel theory about connecting the intended use communications with individual transactions. [ECF No. 484 at 30; ECF No. 501 at 24]. For example, Defendants claim that the Supreme Court in Kordel v. United States held that a product must be accompanied by improper promotional statements in order to prove misbranding. [ECF No. 484 at 30 (citing 335 U.S. 345, 349 (1948)]. But in Kordel, the Supreme Court, although discussing an issue different from intended use, stated that labeling was not required to physically accompany a product because it would "create an obviously wide

[141] Defendants did not request a jury instruction to this effect. See [ECF No. 318 (Defendants' proposed jury instructions)].

loophole to hold that . . . drugs would be misbranded if the literature had been shipped in the same container but not misbranded if the literature left in the next or in the preceding mail." 335 U.S. at 349. Similarly, Defendants cannot avoid culpability by claiming that promotional materials directed to physicians within Massachusetts did not necessarily "accompany" the specific shipments identified in the Indictment. [ECF No. 484 at 30–31]. Articles of Drug for Veterinary Use, also cited by Defendants, states that promotional materials are relevant to intended use as long as they are either currently being distributed or customers continue to rely on representations made in previously distributed materials. 50 F.3d at 500.

The Government provided ample evidence of promotional activities directed specifically at Massachusetts physicians and more nationally regarding the use of the Stratus for drug delivery. [6/20/16 Tr. at 98:18–22 (testimony of Acclarent sales representative Logan stating that she discussed Stratus' use with Kenalog-40 with doctors in her Massachusetts territory "every day"); 6/15/16 Tr. at 124:8–17 (testimony of Dr. Chong, physician at Massachusetts Eye and Ear, stating that Logan described the Stratus as a device that would elute medication slowly, as required for drug delivery); 6/20/16 Tr. at 80:24–81:4, 85:10–23 (discussing an email from Logan to doctors at Massachusetts Eye and Ear that described Stratus as "a reservoir for . . . . temporary direct delivery of a fluid solution")].[142]

[142] Defendants cite two other cases. In Nature Food Centers, Inc. v. United States, the First Circuit rejected a defendant's contention that directions for use on lecture notes satisfied labeling requirements and affirmed the defendant's conviction for misbranding. 310 F.2d 67 (1st Cir. 1962). The opinion did not suggest that there could be no misbranding conviction because the notes were not available where the product was sold. See id. In United States v. An Undetermined Number of Cases, the Second Circuit found there was insufficient evidence to support a misbranding charge for misleading labeling where a book touting a formula was sold near a product that contained that formula and where the parties responsible for each were unrelated entities. 338 F.2d 157 (2d Cir. 1964). This is clearly distinguishable from this case, in which Acclarent made the representations regarding the intended use, failed to file premarket notification for the intended use, and sold the device in question.

Defendants have provided no case law supporting their position and the Court finds that the relevant statute and regulations require no showing of a connection between external communications about using the Stratus for drug delivery and the specific transactions alleged in the Indictment.

4. Whether Adulteration and Misbranding Convictions Are Mutually Exclusive

Defendants next state that their convictions on Counts 9–13 and 14–18, for misdemeanor adulteration and misbranding respectively, are mutually exclusive. [ECF No. 484 at 35]. Counts 9–13 charged Defendants with distribution of an adulterated device based on the failure to file a PMA, and Counts 14–18 charged Defendants with distribution of a misbranded device based on the failure to file an appropriate premarket notification, such as a 510(k). [Indictment ¶¶ 141–42; 143–44]. To obtain permission to market the Stratus for the new intended use of drug delivery, Defendants were required to file a PMA or to submit a premarket notification but they did neither.[143] See [6/7/16 Tr. at 87:10–25, 124:2–14]. Defendants now contend that when a device is required to have either a PMA or a 510(k), but not both, convictions for failing to obtain both are mutually exclusive and cannot stand. [ECF No. 484 at 35].

"[T]he Supreme Court has made it clear that verdict inconsistency in and of itself is not a sufficient basis for vacating a conviction." United States v. Lopez, 944 F.2d 33, 41 (1st Cir. 1991) (citing United States v. Powell, 469 U.S. 57 (1984)). "An inconsistent verdict does not require vacating a criminal conviction as long as the appellate court is satisfied that there was sufficient evidence to sustain the counts of conviction." United States v. Sullivan, 85 F.3d 743, 747 (1st Cir. 1996). For example, if a jury convicts on a conspiracy charge, yet acquits "the

[143] In the remainder of this section, for ease of reading, the Court will refer to permission to sell the Stratus, by which it means permission to market the Stratus for a new intended use.

same defendant on the substantive charge alleged to have been the object of the conspiracy," such an inconsistency does not warrant vacating the conspiracy conviction. Lopez, 944 F.2d at 41.

The rule permitting inconsistent verdicts does not necessarily apply, however, in "a situation where a defendant is convicted of two crimes, where a guilty verdict on one count logically excludes a finding of guilt on the other." Powell, 469 U.S. at 69 n.8 (citing United States v. Daigle, 149 F. Supp. 409, 414 (D.D.C. 1957), aff'd, 248 F.2d 608 (D.C. Cir. 1957)). This narrow exception for so-called mutually exclusive verdicts arises only "where the defendant was 'convicted of two crimes, at least one of which he could not have committed.'" United States v. Maury, 695 F.3d 227, 265 (3d Cir. 2012) (quoting United States v. Gross, 961 F.2d 1097, 1107 (3d Cir. 1992)). In other words, "a conviction as to one of the crimes must negate an element of the other." Id. at 266. "If based on the evidence presented to the jury any rational fact finder could have found a consistent set of facts supporting both convictions, due process does not require that the convictions be vacated." Masoner v. Thurman, 996 F.2d 1003, 1005 (9th Cir. 1993).

Courts have determined that convictions are mutually exclusive where, for example, a defendant is convicted of both embezzlement and larceny for the same underlying conduct, Daigle, 149 F. Supp. at 414, or of both robbery and extortion, United States v. Torres-Concepcion, No. 08-cr-00213, 2010 WL 11505917, at *2 (D.P.R. Mar. 16, 2010) ("[I]t is factually impossible for the evidence to establish that [the defendant] committed both [robbery and extortion] regarding the same property, victim, and occasion."); see also United States v. Bethea, 483 F.2d 1024, 1029–30 (4th Cir. 1973) (convictions for failure to keep draft board advised of current address and failure to report for induction were mutually exclusive, because

one offense required defendant to have provided valid address, while other conviction depended on lack thereof); Thomas v. United States, 314 F.2d 936, 939 (5th Cir. 1963) (convictions of smuggling marijuana into United States and failing to pay transfer tax mutually exclusive where one offense depended on defendant having acquired marijuana outside of United States, while other was predicated on defendant having obtained marijuana within United States).

Adulteration and misbranding concern requirements that a manufacturer must satisfy before introducing a medical device into the market, with the specific requirements of each depending on the classification of the device. The Medical Device Amendments of 1976 "classifies medical devices in three categories based on the risk that they pose to the public." Medtronic, 518 U.S. at 476; see also 21 U.S.C. § 360c(a)(1). Every new medical device introduced into the market after 1976 is initially classified as a Class III device. 21 U.S.C. § 360c(f)(1). To obtain permission to sell a Class III device, a manufacturer must ordinarily go through the PMA process, which consists of a "rigorous" review by the FDA that takes an average of 1,200 hours to complete. Medtronic, 518 U.S. at 477.

Alternatively, a manufacturer may submit a "premarket notification" to the FDA, most commonly in the form of a 510(k) submission, on the basis that the device is "substantially equivalent" to an existing device. Id. In contrast to the PMA process, the 510(k) review is much faster, taking an average of about 20 hours. Id. If the FDA grants the 510(k) application, the device is reclassified into Class I or II. 21 U.S.C. §§ 351(f)(1)(B), 360c(f). A Class III device is deemed to be adulterated unless the manufacturer has obtained a PMA. 21 U.S.C. § 360c(f)(2)(B)(ii); see also 21 U.S.C. § 360e. In addition, a Class III device is misbranded unless the manufacturer has filed a premarket notification, such as a 510(k); however, if the manufacturer has a PMA application pending, the premarket notification is not required. 21

U.S.C. §§ 352(o), 360(k); 21 C.F.R. § 807.81.

Defendants claim that because a device is required to have either a PMA or a 510(k) for a particular intended use, but not both, their convictions for adulteration and misbranding are mutually exclusive. [ECF No. 484 at 35]. They contend that the only way the jury could have found Defendants guilty of adulteration was to conclude that the Stratus was required to have a PMA, but not a 510(k), and that conversely, the jury could have only found Defendants guilty of misbranding if they determined that the device was required to have a 510(k), but not a PMA. [Id. at 38–39].

There is no inherent contradiction in being convicted of distributing a device that is both adulterated and misbranded, despite Defendants' attempts to suggest otherwise. The jury could have reasonably found that the Stratus was adulterated because it was a Class III device for which no PMA had been obtained, see 21 U.S.C. §§ 360c(f)(2)(B)(ii), 360e, and that the Stratus was misbranded because it was a Class III device for which the manufacturer had not filed a premarket notification, such as a 510(k), 21 U.S.C. §§ 352(o), 360(k). Because a pending PMA application can provide the requisite premarket notice, relieving the manufacturer of the need to file a 510(k), 21 C.F.R. § 807.81, the filing of a PMA would have ensured that the Stratus was neither adulterated nor misbranded. Because Defendants did not file a PMA, however, the device was adulterated, and because the defendants filed neither a 510(k) nor a PMA, the device was misbranded.

Essentially, Defendants imply that because filing a PMA would have negated an element of both offenses, the convictions are mutually exclusive. See [ECF No. 484 at 41]. For convictions to be mutually exclusive, however, an element that must be present to convict on one offense has to necessarily negate an element that must be present to convict on the other offense.

See Maury, 695 F.3d at 265 (mutually exclusive conviction present only when "a conviction as to one of the crimes must negate an element of the other"). Defendants have not identified such an element here, nor can they. Failure to file a PMA is the crucial element of adulteration, and failure to file a 510(k) or a PMA are the key elements of misbranding. Defendants' conduct could satisfy the elements of both crimes. The fact that adulteration and misbranding share some common elements does not mean that Defendants can only be convicted of one or the other.

In addition, Defendants assert that the only way they could be convicted of both adulteration and misbranding would be if the Stratus were simultaneously categorized as both Class I and Class III, because, as Defendants frame it, a manufacturer must file a 510(k), on a device that is classified as Class I or II, whereas a device that requires a PMA must be a Class III device.[144] [ECF No. 484 at 40]. This attempt to flip the statutory scheme on its head is not persuasive. Devices are not classified according to whether or not a PMA or premarket notification is required; rather, devices are assigned to Class I, II, or III based on their risk to the public. Medtronic, 518 U.S. at 476–77. The requirements that must be satisfied by a manufacturer to sell a device depend on how the device is categorized, not the other way around. Id.; 21 U.S.C. § 360c(a)(1). As relevant here, the manufacturer of a Class III device must either

[144] Defendants rely in part on an FDA webpage to support their argument that a Class III device does not require a 510(k), but they quote selectively from that page. The relevant text, in its entirety, reads: "For Class III devices, a premarket approval application (PMA) will be required unless your device is a preamendments device (on the market prior to the passage of the medical device amendments in 1976, or substantially equivalent to such a device) and PMA's have not been called for. In that case, a 510k will be the route to market." Classify Your Medical Device, FDA, https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/ClassifyYourDevice/default.htm (last updated February 7, 2020). This text simply reiterates the same scheme laid out supra: that a manufacturer need not submit a PMA if the device is "substantially equivalent" to an existing device, in which case the manufacturer should file a 510(k). Furthermore, even if the webpage stated otherwise, a webpage may provide clarification, but is not legal authority.

file a 510(k) or have a PMA application pending to avoid misbranding. 21 U.S.C. §§ 352(o), 360(k); 21 C.F.R. § 807.81. Thus, it is not true that only Class I or II devices require a 510(k). A Class III device requires a 510(k) to prevent misbranding, unless a substitute document that satisfies the statutory requirements has been filed. 21 C.F.R. § 807.81. Accordingly, there is no inherent contradiction in Defendants' adulteration and misbranding convictions, which are both accurately premised on the Stratus' classification as a Class III device.

Thus, Defendants' First Amendment, Due Process, sufficiency of the evidence, and inconsistent verdict arguments are all insufficient to overcome their burden to demonstrate "that the evidence presented at trial, even when viewed in the light most favorable to the government, did not suffice to prove the elements of the offenses beyond a reasonable doubt." See Acevedo, 882 F.3d at 257. Viewing the evidence and "all plausible inferences drawn therefrom, in the light most favorable to the verdict," the Court finds that acquittal under Federal Rule of Criminal Procedure 29 is not warranted. See Meléndez-González, 892 F.3d at 17.

IV. NEW TRIAL UNDER RULE 33

A. Legal Standard

On a motion for a new trial under Federal Rule of Criminal Procedure 33, "the court may vacate any judgment and grant a new trial if the interest of justice so requires." Fed. R. Crim. P. 33(a). "In considering a motion for a new trial, district courts may 'weigh the evidence and evaluate the credibility of witnesses, . . . [but] the remedy of a new trial is sparingly used, and then only where there would be a miscarriage of justice and where the evidence preponderates heavily against the verdict.'" Merlino, 592 F.3d at 32 (quoting United States v. Wilkerson, 251 F.3d 273, 278 (1st Cir. 2001)). "[I]t is only where exceptional circumstances can be demonstrated that the trial judge may intrude upon the jury function of credibility assessment."

Id. at 32–33 (internal quotation marks omitted). "A district court 'judge is not a thirteenth juror who may set aside a verdict merely because he would have reached a different result.'" United States v. Rivera-Rangel, 396 F.3d 476, 486 (1st Cir. 2005) (quoting United States v. Rothrock, 806 F.2d 318, 322 (1st Cir. 1986)).

In addition, on a Rule 33 motion the Court may "consider whether its evidentiary rulings at trial were correct." United States v. DiMasi, 810 F. Supp. 2d 347, 362 (D. Mass. 2011) (citing Wilkerson, 251 F.3d at 279–80). "However, a new trial is justified only if an error concerning the admission of evidence was made and the error was not 'harmless,'" meaning that, even if an error was made, "it is highly probable that the error did not contribute to the verdict." Id. (quoting Wilkerson, 251 F.3d at 280).

Where a defendant raises allegations of prosecutorial misconduct, the Court must consider whether "several incidents of prosecutorial misconduct, none of which would separately constitute grounds for mistrial, could have a cumulative impact on the jury sufficient to affect the trial's outcome." United States v. Wihbey, 75 F.3d 761, 773 (1st Cir. 1996). In evaluating the impact of these claims, courts

> weigh several factors in determining "whether prosecutorial misconduct has so poisoned the well that a new trial is required: (1) the severity of the misconduct; (2) the context in which it occurred; (3) whether the judge gave any curative instructions and the likely effect of such instructions; and (4) the strength of the evidence against the defendant."

United States v. Robinson, 473 F.3d 387, 398 (1st Cir. 2007) (quoting United States v. Casas, 425 F.3d 23, 38 (1st Cir. 2005)). These factors "are meant merely to guide the court's inquiry into whether the prosecutor's improper comments have undermined the fairness of the trial." United States v. Carpenter, 494 F.3d 13, 23 (1st Cir. 2007).

B. Defendants' Asserted Grounds for a New Trial

Defendants claim that the Government's use of improper evidence warrants a new trial based on the pervasive effect of the errors taken together. [ECF No. 484 at 5, 41]. The Government disputes the nature of Defendants' claims as well as the effect of the alleged errors on the outcome at trial. [ECF No. 497 at 49–57]. As discussed below, Defendants' claims include six specific grounds for relief. [ECF No. 484 at 41–53].

1. Misleading and Improper Arguments About the Safety Profile of the Stratus

Defendants first argue that the Government presented "misleading, unsupported, and inflammatory assertions" to the effect that Defendants' conduct placed patients at risk. [ECF No. 484 at 41–42]. The Government counters this by stating that it presented necessary information about how the device worked and its potential risks. [ECF No. 497 at 50–52].

Defendants mischaracterize certain statements made by the Government. For example, during its opening statement the Government described how a doctor would insert a Stratus using a "super sharp needle" called a trocar. [6/7/16 Tr. at 28:14]. This description was accurate and was also consistent with the testimony of Defendants' own witnesses, one of whom, Dr. Catalano, described the insertion process as follows: "this little metal spear, if you will, was used to pierce the bone. It's thin bone; it's not heavy bone like your skull." [7/12/16 Tr. at 11:17–18].[145] Thereafter, when discussing a "paper-thin barrier," the Government was not, as Defendants suggest, making an association between that area of the sinuses and the needle inserting the device to suggest that insertion of the device was dangerous, but was instead discussing the location of drug delivery: "There's a big difference between doing that and

[145] Defendants' witness, Dr. Hoisington, testified that he did not use a trocar to insert the Stratus due to safety concerns. [7/8/16 Tr. at 119:9–120:4].

releasing the drug as a liquid directly into a space inside your head that is located right next to your eyes and separated from your brain by only a paper-thin barrier." [6/7/16 Tr. at 29:17–20].

The Government did, as Defendants state, elicit testimony about the risks of inserting such a device into a patient, but these risks were associated with physician error, rather than the device itself. [ECF No. 484 at 42 (citing testimony of Government witness Dr. Armstrong); 6/8/16 Tr. at 151:21–23 (testimony of Dr. Armstrong: "Well, the—the intuitive fears that all of—that I would have as a potential user of the device, is I hope I don't stick this sharp device in the wrong place.")]. With regard to the use of the device itself, Defendants cite several risks discussed by the Government without denying the veracity of those risks. [ECF No. 484 at 42–43 (discussing low rate of adverse effects without denying risks)].

Defendants had the opportunity to cross-examine witnesses and challenge any allegations regarding the safety and risk profile of the Stratus. Defendants also took the opportunity to object to aspects of this evidence and in certain instances the Court limited the Government's presentation of this evidence under Federal Rule of Evidence 403. See, e.g., [6/14/16 Tr. at 119:19–24, 121:20–22]. At root, the Stratus *was* inserted with a sharp needle into an area of the sinuses that was near to the brain: both parties discussed the method of inserting the device into patients and both used language consistent with the procedure. There is therefore no reasonable argument that the Government's presentation of evidence on this issue rose to a level that would justify a finding of prosecutorial misconduct or otherwise warrant a new trial.

In addition to allegedly inappropriate comments about safety, Defendants also reference comments made during the Government's closing and rebuttal arguments. [ECF No. 484 at 44]. For example, during the Government's closing, when discussing the general purpose of the FDA approval process, the Government stated:

> Because there is a system in place to check products first before they get tested on the American population, before the American population gets to be used as guinea pigs. And everyone who has a great idea about a drug or medical device, they have to go through the process.

[7/14/16 Tr. at 130:1–6]. Although the jury could have drawn an inference with regard to Defendants' conduct, the Government did not specifically state that Defendants had treated patients like guinea pigs. Further, Defendants requested and the Court provided curative instructions to the jury close in time to when the statement was made. [7/14/16 Tr. at 141:10–20].[146] "[C]urative instructions are 'ordinarily an appropriate method of preempting a mistrial.'" United States v. Peake, 804 F.3d 81, 95 (1st Cir. 2015) (quoting United States v. Trinidad-Acosta, 773 F.3d 298, 308 (1st Cir. 2014)). In sum, the Court finds that the Government's statement was not unduly inflammatory in the broader context of the Government's closing statements which concerned the purposes of requiring companies to seek FDA approval for new devices, and further, that the Court's curative instructions were sufficient. See [7/14/16 Tr. at 130:1–17, 141:10–20]; Peake, 804 F.3d at 95 (holding that, where "the district court acted timely and decisively to instruct the jury in great detail to disregard the offending statements" made by the government during its opening statement and where the evidence weighed heavily in favor of the verdict, a new trial was unwarranted).

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[146] The Court instructed the jury as follows:

> At the close of her closing, Ms. Bloom made some comments about incentivizing the behaviors of others and generalizing as to why following the FDA process is important. I want to caution you that you must decide this case solely based on the facts presented to you in this courtroom and based on the conduct of these defendants. You're not to be fueled by any considerations of the system, device testing or the mission of the FDA.

[7/14/16 Tr. at 141:10–17]. The Court asked the parties if they felt the instruction was sufficient and both parties agreed that it was. [Id. at 141:18–20].

Finally, Defendants allege that the Government's statement during rebuttal in response to arguments about the lack of evidence of patient harm was prejudicial and inflammatory. [ECF No. 484 at 44–45]. Defendants quote only a snippet of the Government's statement, however, and the full context indicates that the Government was responding to a statement made during defense counsel's closing: "Now, it is true, Mr. Weingarten said, [n]o one was hurt, so why are we here in criminal court? But just because this time no one died doesn't mean the process doesn't matter." [7/15/16 Tr. at 132:13–15]. This was a fair rebuttal to counsel for Defendant Facteau's closing argument where he said: "[B]ut the point, to me, the real issue is the potential harm done, and none was shown." [7/15/16 Tr. at 84:24–25]. The Government's rebuttal statement was not a gratuitous comment meant to inflame the jury, but rather a relevant counterpoint to statements made by counsel for Defendant Facteau during his closing. See United States v. Machor, 879 F.2d 945, 956 (1st Cir. 1989) ("Although the government is not entitled to 'fight fire with fire' at all costs, the fact that defense counsel comments 'invited a reply' is a relevant consideration.").

A new trial is not justified where, as here, any errors in the admission of evidence concerning the safety of the device were harmless in that it is unlikely those errors contributed to the verdict. See DiMasi, 810 F. Supp. 2d at 362 (quoting Wilkerson, 251 F.3d at 280). As to the Government's remarks during closing and rebuttal statements, the Supreme Court has "warned courts against giving too much weight to stray remarks in the course of a closing argument or assuming that the jury would interpret each and every statement in the most damaging manner possible." Dagley v. Russo, 540 F.3d 8, 17 (1st Cir. 2008) (citing Donnelly v. DeChristoforo, 416 U.S. 637, 647 (1974)). Defendants have not plausibly alleged that the Government was not entitled to present evidence of the safety of the device when Defendants did the same and also

had ample opportunity to cross-examine the Government's witnesses and challenge any alleged inaccuracies. Nor can Defendants select snippets from the record, taken out of context, to fashion a colorable claim of inflammatory remarks made to prejudice the jury. The Court finds no merit in Defendants' allegations with regard to prosecutorial misconduct connected to the statements, referenced supra, concerning the safety profile of the Stratus.

2. Refusal to Immunize Debra Cogan

Defendants argue that they were unfairly prejudiced by the Government's refusal to immunize Debra Cogan, a senior regulatory employee at Acclarent. [ECF No. 484 at 45–46]. Defendants believe that Cogan's testimony was "critical" to their misdemeanor convictions because she had insight into how Acclarent regulatory employees attempted to comply with the FDA rules regarding off-label discussions with physicians. [Id. at 45]. The Government, in turn, argues that they had no obligation to immunize Cogan and that Defendants could have called any of Acclarent's five other regulatory and legal personnel to testify on the same matters. [ECF No. 497 at 52].

Due Process acts as a constraint on prosecutors' decisions regarding immunity but "operates at the margins of the prosecutor's discretion and takes on a practical significance only when the prosecutor deliberately aspires to distort the factfinding process." United States v. Chan Hok Shek, No. 08-cr-10317, 2010 U.S. Dist. LEXIS 119484, at *28 (D. Mass. Nov. 10, 2010) (citing Curtis v. Duval, 124 F.3d 1 (1st Cir. 1997)). Defendants cite no evidence of bad faith on the part of the Government in choosing not to immunize Cogan, nor do they refute the

Government's claim that there were several other potential witnesses that Defendants could have called to elicit similar testimony. See [ECF No. 484 at 45–46].[147]

Further, whether Acclarent employees followed their regulatory department's rules regarding off-label communications with physicians is irrelevant to the Defendants' convictions. As discussed at length supra, Defendants were not convicted for their communications or their employees' communications with physicians, but rather were convicted for failing to obtain PMA approval or to submit premarket notification for a new intended use. Cogan's testimony regarding approved off-label communications with physicians would not have explained why Defendants avoided seeking FDA approval for a new intended use for the Stratus device or otherwise negate any element of the offenses of conviction. In addition, as the Government notes, the testimony of Cogan was primarily relevant to Defendants' good faith defense to the fraud charges on which they were acquitted. [ECF No. 497 at 52]; United States v. Berroa, 856 F.3d 141, 160 (1st Cir. 2017) (finding no misconduct in refusing to immunize a witness where their testimony would have been of minimal value and where other witnesses were available to provide similar testimony).

3. Implications Regarding On-Label Use of Stratus

Defendants next contend that the Government improperly implied that no doctor used the Stratus with saline and that the device did not function purely as a spacer. [ECF No. 484 at 46]. The Government, in contrast, states that because they were entitled to ask witnesses about their

[147] The Government improperly stated during rebuttal that Defendants had a right to call witnesses to contradict the Government's case, without naming Cogan in particular. [7/15/16 Tr. at 124:9–11]. The Court instructed the jury to disregard this statement. [Id. at 161:20–162:2]; see United States v. Dwyer, 238 F. App'x 631, 655–56 (1st Cir. 2007) (concluding that any harm from prosecution's improper statements in rebuttal argument was remedied by court's supplemental instructions to jury).

on- and off-label use of the Stratus, this line of questioning was not improper. [ECF No. 497 at 54].

In support of their argument, Defendants state that the Government elicited testimony from witnesses that suggested that no doctor used or would have used the Stratus with saline, despite knowing prior to trial that doctors did use the Stratus with saline and then hearing testimony at trial from defense witness Dr. Hoisington regarding his own use of the Stratus with saline. [ECF No. 484 at 46]. Dr. Hoisington, formerly a member of Acclarent's SAB, also testified that he and other doctors believed the Stratus had value as a spacer without the use of saline or Kenalog-40. [Id. at 46]. As the Government points out, however, Dr. Hoisington seemingly changed his position on this issue prior to trial as reflected in his trial testimony. [ECF No. 497 at 54]. During a pre-trial interview with federal agents, Dr. Hoisington acknowledged that he used the Stratus with Kenalog-40, and further, a video shown to jurors at trial also showed Dr. Hoisington promoting the Stratus as a "drug delivery device" and explaining how it could be used with Kenalog-40. [7/8/16 Tr. at 183:1–13 (interview with agents); 6/8/16 Tr. at 45:24–46:4, 49:7–10, 49:17–50:5, 54:17–55:6 (video)]. The Government also introduced into evidence a May 2008 email in which Dr. Hoisington wrote, "I am not sure why I would put something into the ethmoid [sinus] that has disease present and then only put saline in. Does this make any sense to you?" [6/23/16 Tr. at 85:1–16]. In addition, Dr. Hoisington confirmed that he was unable to identify a patient file in which he used the Stratus with saline. [7/8/16 Tr. at 182:20–22].[148]

[148] Defendants fail to note that two of their own witnesses, Drs. Catalano and Levine, also testified that that they never used the device with saline and did not know of any doctors who used the device with saline. [7/12/16 Tr. at 65:18–66:3, 66:20–22, 67:2–5, 67:11–17; 7/11/16 Tr. at 139:23–140:1, 229:3–230:2].

The Government presented sufficient evidence for the jury to decide beyond a reasonable doubt that Defendants' actions demonstrated an objective intent with regard to the use of the Stratus for drug delivery. See supra Section II; see also Merlino, 592 F.3d at 32 ("[T]he remedy of a new trial is sparingly used, and then only where there would be a miscarriage of justice and where the evidence preponderates heavily against the verdict."). Even if some physicians used the device for an on-label purpose, thereby allowing an inference that at least some physicians received on-label information about the device, the Government provided ample evidence demonstrating that the Defendants were actively marketing the product for an off-label use for which they had not obtained FDA approval. See, e.g., [6/8/16 Tr. at 49:1–50:5 (trial testimony of Dr. Armstrong, stating that representatives of Acclarent promoted off-label use at a marketing event); 6/9/16 Tr. at 210:24–211:19 (discussing GX2424, a sell sheet containing a photograph of the Stratus being used with Kenalog-40 and no discussion of use of the device with saline); 6/10/16 Tr. at 98:16–18 (testimony of sales representative Vanderkarr stating that she never heard of a physician using the Stratus with saline)].

For the purposes of a Rule 33 motion, "it is only where exceptional circumstances can be demonstrated that the trial judge may intrude upon the jury function of credibility assessment." Merlino, 592 F.3d at 32–33. Exceptional circumstances are not present here, where jurors made reasonable credibility determinations as between witnesses who claimed to have used the Stratus with saline and as a standalone spacer and witnesses who said they never used the device for those purposes, but instead used it solely for drug delivery. United States v. Lipscomb, 539 F.3d 32, 40 (1st Cir. 2008) ("Credibility determinations are squarely within the jury's province, and we will not disturb them unless there is no reasonable way a jury could have found the witnesses believable.").

Finally, the Government was entitled to present testimony indicating that few, if any, doctors used the Stratus as a spacer or with saline in order to support their alternative theory regarding Defendants' allegedly false and misleading conduct. Mubayyid, 658 F.3d at 70 ("It is well established that an indictment may charge alternative theories of guilt in the conjunctive . . . ."). Evidence supporting the alternative theory was not improper and the jury's verdict indicates that it was not confused by the presentation of evidence in support of the Government's various theories.

4. Failure to Correct Incorrect Testimony

Defendants allege that the Government failed to correct testimony given by one of its witnesses, Steffen, after another witness, Convery, contradicted that testimony. [ECF No. 484 at 48]. The Government responds that Convery's testimony wavered and that his testimony did not necessarily indicate that Steffen's testimony was false. [ECF No. 497 at 55].

Steffen testified first and stated that Convery had presented training slides to Acclarent's new hires in early 2010 that included discussion of the Stratus as a drug delivery device. [6/14/16 Tr. at 77:14–17, 88:11–89:3, 89:15–20]. Convery testified several days later and first testified that he could not remember the specifics of individual presentations he had given because he had presented the information many times. [6/16/16 Tr. at 173:13–174:6]. When asked again, Convery said that "as far as [he] kn[e]w," a presentation dated April 2010, which did not include a reference to the Stratus, was the one he presented to Steffen. [Id. at 176:24–177:1].

Defendants cast Steffen's testimony as false, rather than acknowledging that witnesses can and often do have differing memories of events and that such differences alone do not prove that one witness is lying, or require the Government to determine if one witness or the other

testified falsely. See [ECF No. 484 at 48–50]; United States v. Doherty, 867 F.2d 47, 70 (1st Cir. 1989) ("Neither Napue nor any other decision prohibits a prosecutor from calling witnesses who will present conflicting stories."). Convery was equivocal regarding what information he presented in April 2010, whereas Steffen felt confident about what he had heard from Convery. Each side was given the opportunity to cross-examine and probe each witness's memory of events and the jury was free to determine the credibility of each witness. Lipscomb, 539 F.3d at 40; Casas, 425 F.3d at 45 ("[S]uch conflicts are a matter to be explored on cross-examination . . . and the credibility of each account is for the jury to determine."). Here, the Government's decision to introduce testimony from witnesses whose recollections differed was not evidence of prosecutorial misconduct.

5. Inducement of a Witness to Place Defendant Fabian at Meetings

In one sentence in their memorandum in support of a new trial, Defendants claim that the Government improperly sought testimony from Barrigar regarding Defendant Fabian's attendance at meetings the Government knew Defendant Fabian did not or could not have attended. [ECF No. 484 at 50]. The Government notes that "Mr. Barrigar was always clear that he was uncertain as to his memory," signaling to the jury that they would need to assess his credibility for themselves. See [ECF No. 497 at 56 (citing 6/22/16 Tr. at 21:12–14 (Barrigar stating, "I don't know for sure" when asked if Defendant Fabian was in a meeting))]. During the Government's direct examination, Barrigar said he believed Defendant Fabian was present at an August 14, 2007 meeting, but his testimony was promptly corrected on cross examination when he was reminded that Defendant Fabian had not joined Acclarent until several days after August 14 and therefore could not have been present at the meeting. [6/23/16 Tr. at 164:8–18]; see also [7/7/16 Tr. at 220:19–20 (stipulation as to Defendant Fabian's dates of employment)].

The Government was not prohibited from asking witnesses whether Defendants were present at particular meetings, and failing to recall Defendant Fabian's start date when eliciting testimony from a single witness does not rise to the level of prosecutorial misconduct. In questioning Barrigar regarding Defendant Fabian's attendance at these meetings, the Government's conduct, even if liberally construed as misconduct, did not rise to the level of a "'particularly egregious error[]' . . . that 'seriously affect[ed] that fairness, integrity or public reputation of judicial proceedings.'" United States v. Hodge-Balwing, 952 F.2d 607, 611 (1st Cir. 1991) (quoting United States v. Young, 470 U.S. 1, 15 (1985); see also United States v. Gentles, 619 F.3d 75, 81 (1st Cir. 2010) (holding that "misconduct alone is insufficient to reverse a conviction absent a showing of prejudice").

6. Evidence Regarding Acclarent Trade Show Booth

Defendants' final asserted ground for a new trial is the Government's decision to elicit testimony regarding Acclarent's use of a 2008 trade show booth that was designated for physicians working internationally to promote the Stratus for off-label use to U.S.-based physicians. [ECF No. 484 at 50–51]. Defendants claim that the Government improperly used this testimony to suggest that this promotion was improper despite the FDA's position that promotion to physicians practicing outside of the United States regarding uses approved outside of the United States is permissible. [Id. at 50–51]. The Government says that the testimony regarding the trade show booth was used to prove that physicians based in the United States "were redirected to the [international] booth for a demonstration about an unapproved use, rather than instructed about the on-label use at the US booth." [ECF No. 497 at 57].

In support of their position, Defendants cite to a declaration from their expert, Jeffrey Shapiro, regarding the FDA's position on marketing within the United States for uses that are

only approved internationally. [ECF No. 484 at 51; ECF No. 485-1 (Shapiro Declaration)]. As the Government notes, however, prior to trial the Government identified an inconsistency in Shapiro's position by citing a 1997 article in which he wrote that "if a device is cleared or approved in this country for one use, it cannot be displayed at trade shows for another use that is only approved abroad." [ECF No. 497 at 57 n.65 (quoting Shapiro, Jeffrey K., Displaying Investigational and Unapproved Medical Devices According to FDA Policy at 4, Medical Device & Diagnostic Industry (Oct. 1997)]. Defendants cite no support for their statements regarding the FDA's position beyond Mr. Shapiro's declaration. [ECF No. 484 at 51]. Shapiro's declaration, in turn, cites his experience and a 2016 conversation with an FDA employee, but the record of that conversation does not address the FDA's position regarding the off-label promotion of a product that already has an FDA-approved use, or the FDA's position regarding directing U.S.-based physicians to a booth that is promoting off-label uses. See [ECF No. 485-1 at 11–12, 41]. Given the Government's purpose in eliciting this testimony—demonstrating that Acclarent employees directed U.S. physicians to a booth at which they could learn about off-label uses—the Government's use of this testimony was not improper. See [6/10/16 Tr. at 56:19–25 (Vanderkarr testimony regarding directing individuals to the international booth for off-label questions)]. Taken together, the actions of the Government concerning the booth did not rise to the level of misconduct as alleged by Defendants.

7. Summary

In conclusion, even assuming misconduct occurred, using the First Circuit's analysis in United States v. Robinson, the majority of the factors weigh in favor of a finding that Defendants were not prejudiced due to the minor nature of any infractions, the curative instructions provided by the Court, and the strength of the evidence against Defendants. 473 F.3d at 398. Even when

viewed cumulatively, these purported incidents of misconduct were unlikely to have had an "impact on the jury sufficient to affect the trial's outcome." Wihbey, 75 F.3d at 773. "[T]he remedy of a new trial is rarely used; it is warranted only where there would be a miscarriage of justice or where the evidence preponderates heavily against the verdict." Casas, 425 F.3d at 39 (quoting United States v. Rodríguez-De Jesús, 202 F.3d 482, 486 (1st Cir. 2000)). As those exceptions are not present in this case, Defendants' motion for a new trial, [ECF No. 437], is DENIED.

V. CONCLUSION

Accordingly, for the reasons explained above, Defendants' motion for acquittal or a new trial, [ECF No. 437], is DENIED.

SO ORDERED.

September 14, 2020

/s/ Allison D. Burroughs

ALLISON D. BURROUGHS
U.S. DISTRICT JUDGE